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Group art therapy as an adjunctive treatment for people with schizophrenia: a randomised controlled trial (MATISSE)

MJ Crawford, H Killaspy, TR Barnes, B Barrett, S Byford, K Clayton, J Dinsmore, S Floyd, A Hoadley, T Johnson, E Kalaitzaki, M King, B Leurent, A Maratos, FA O'Neill, D Osborn, S Patterson, T Soteriou, P Tyrer and D Waller on behalf of the MATISSE project team

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Group art therapy as an adjunctive treatment for people with schizophrenia: a randomised controlled trial (MATISSE)

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Abstract

Group art therapy as an adjunctive treatment for people with schizophrenia: a randomised controlled trial (MATISSE)

MJ Crawford,[1]* H Killaspy,[2] TR Barnes,[1] B Barrett,[3] S Byford,[3] K Clayton,[4] J Dinsmore,[5] S Floyd,[6] A Hoadley,[2] T Johnson,[7] E Kalaitzaki,[8] M King,[2] B Leurent,[8] A Maratos,[9] FA O'Neill,[5] D Osborn,[2] S Patterson,[1] T Soteriou,[6] P Tyrer[1] and D Waller[1] on behalf of the MATISSE project team

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Objective: To examine the clinical effectiveness and cost-effectiveness of referral to group art therapy plus standard care, compared with referral to an activity group plus standard care and standard care alone, among people with schizophrenia.

Design: A three-arm, parallel group, single-blind, pragmatic, randomised controlled trial. Participants were randomised via an independent and remote telephone randomisation service using permuted blocks, stratified by study centre.

Setting: Study participants were recruited from secondary care mental health and social services in four UK centres.

Participants: Potential participants were aged 18 years or over, had a clinical diagnosis of schizophrenia, confirmed by an examination of case notes, and provided written informed consent. We excluded those who were unable to speak sufficient English to complete the baseline assessment, those with severe cognitive impairment and those already receiving arts therapy.

Interventions: Group art therapy was delivered by registered art therapists according to nationally agreed standards. Groups had up to eight members, lasted for 90 minutes and ran for 12 months. Members were given access to a range of art materials and encouraged to use these to express themselves freely. Activity groups were designed to control for the non-specific effects of group art therapy. Group facilitators offered various activities and encouraged participants to collectively select those they wanted to pursue. Standard care involved follow-up from secondary care mental health services and the option of referral to other services, except arts therapies, as required.

Main outcome measures: Our co-primary outcomes were global functioning (measured using the Global Assessment of Functioning Scale – GAF) and mental health symptoms (measured using the Positive and Negative Syndrome Scale – PANSS) at 24 months. The main secondary outcomes were level of group attendance, social functioning, well-being,

health-related quality of life, service utilisation and other costs measured 12 and 24 months after randomisation.

Results: Four hundred and seventeen people were recruited, of whom 355 (85%) were followed up at 2 years. Eighty-six (61%) of those randomised to art therapy and 73 (52%) of those randomised to activity groups attended at least one group. No differences in primary outcomes were found between the three study arms. The adjusted mean difference between art therapy and standard care at 24 months was –0.9 [95% confidence interval (CI) –3.8 to 2.1] on the GAF Scale and 0.7 (95% CI –3.1 to 4.6) on the PANSS Scale. Differences in secondary outcomes were not found, except that those referred to an activity group had fewer positive symptoms of schizophrenia at 24 months than those randomised to art therapy. Secondary analysis indicated that attendance at art therapy groups was not associated with improvements in global functioning or mental health. Although the total cost of the art therapy group was lower than the cost of the two comparison groups, referral to group art therapy did not appear to provide a cost-effective use of resources.

Conclusions: Referring people with established schizophrenia to group art therapy as delivered in this randomised trial does not appear to improve global functioning or mental health of patients or provide a more cost-effective use of resources than standard care alone.

Trial registration: Current Controlled Trials ISRCTN 46150447.

Funding: This project was funded by the NIHR Health Technology Assessment programme and will be published in full in *Health Technology Assessment*; Vol. 16, No. 8. See the HTA programme website for further project information.

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List of abbreviations

AD-SUS	Adult Service Use Schedule
BSL	baseline
CI	confidence interval
CONSORT	Consolidated Standards of Reporting Trials
CEAC	cost-effectiveness acceptability curve
CPN	community psychiatric nurse
CSQ	Client Satisfaction Questionnaire
EQ-5D	European Quality of Life-5 Dimensions
GAF	Global Assessment of Functioning Scale
GP	general practitioner
HRQoL	health-related quality of life
ICC	intraclass correlation coefficient
ICER	incremental cost-effectiveness ratio
ITT	intention to treat
MATISSE	Multicentre evaluation of Art Therapy In Schizophrenia: Systematic Evaluation
NICE	National Institute for Health and Clinical Excellence
OPCRIT	operational criteria (a checklist for psychotic and affective illness)
PANSS	Positive and Negative Syndrome Schizophrenia Scale
PSSRU	Personal Social Services Research Unit
QALY	quality-adjusted life-year
RCT	randomised controlled trial
SD	standard deviation
SES	Service Engagement Scale
SFQ	Social Function Questionnaire

All abbreviations that have been used in this report are listed here unless the abbreviation is well known (e.g. NHS), or it has been used only once, or it is a non-standard abbreviation used only in figures/tables/appendices, in which case the abbreviation is defined in the figure legend or in the notes at the end of the table.

Executive summary

Background

Although pharmacotherapy can reduce the symptoms of schizophrenia, many people with this condition continue to experience poor mental health and social functioning. It has been argued that creative therapies could provide a complementary approach to improving mental health through helping people to express themselves, and develop self-awareness and insight. Group art therapy has been widely used as an adjunctive treatment for people with schizophrenia, but there have been few attempts to examine its clinical effects and cost-effectiveness has not been examined.

Objectives

We undertook a pragmatic, randomised controlled trial (RCT), which was designed to achieve the following objectives:

- compare the effects of referral to group art therapy plus standard care with referral to an active control group plus standard care or to standard care alone on the mental health and global functioning of people with schizophrenia
- examine the impact of referral to weekly group art therapy on well-being, health-related quality of life (HRQoL) and satisfaction with care over a 24-month period
- examine whether or not any benefits associated with art therapy exceeded those associated with an active control group
- compare the costs and cost-effectiveness of group art therapy, active control treatment and standard care over a 2-year period.

Methods

The study was a single-blind, parallel-group RCT of referral to group art therapy plus standard care, referral to an activity group plus standard care or standard care alone. Participants were randomised via an independent and remote telephone randomisation service using permuted blocks, stratified by site. The block size was randomly assigned between 3 and 6. Each participant within the block was randomly assigned to one of the three treatments in proportion to the size of the block. Participants and clinical staff were aware of to which arm of the trial participants were allocated, but all interviews were conducted by researchers masked to allocation status. Art therapy and activity groups were run on a weekly basis by a lead therapist and a co-facilitator and were made available to participants for an average of 12 months.

Participants

Study participants were recruited from inpatient and community-based mental health and social care services at four centres in England and Northern Ireland. Participants were aged 18 years or over and had a clinical diagnosis of schizophrenia, confirmed by an examination of case notes using operationalised criteria. To take part in the study, potential participants had to be willing to take part in groups and to provide written informed consent. We excluded those with severe cognitive impairment, those who were unable to speak sufficient English to complete the baseline (BSL) assessment and those who were already attending art or other creative therapies.

Main outcome measures

The primary outcomes for the study were global functioning [measured using the Global Assessment of Functioning Scale (GAF)] and symptoms of schizophrenia [measured using the Positive and Negative Syndrome Scale (PANSS)], assessed at 24 months. Secondary outcomes were global functioning and mental health symptoms measured at 12 months, as well as levels of group attendance, social functioning [measured using the Social Function Questionnaire (SFQ)], concordance with prescribed medication (measured using the Morisky Scale), satisfaction with care (measured using the Client Satisfaction Questionnaire), mental well-being (measured using the General Well-Being Scale), HRQoL [measured using the five-item EuroQol scale 'European Quality of Life-5 Dimensions' (EQ-5D)] and resource use (measured using a modified version of the Adult Service Use Schedule), assessed at 12 and 24 months after randomisation.

Study procedures

Health- and social-care professionals, working on inpatient units or in community teams, day centres and rehabilitation and residential units, identified potential participants. Researchers and clinical studies officers of the UK Mental Health Research Network met those who had given verbal consent to be approached about the study, assessed eligibility, provided written and verbal information, and obtained written consent. Following completion of the BSL assessments, participants were then randomised. Participants, their key worker and their general practitioner were notified of allocation status by an independent administrator. The administrator simultaneously informed local art therapists or activity group facilitators of the participants' allocation status, so that arrangements could be made for the participants to receive their allocated intervention. Researchers involved in collecting follow-up data remained masked.

Those randomised to group art therapy were offered weekly sessions of 90 minutes' duration for an average of 12 months. Art therapy was conducted in keeping with recommendations of the British Association of Art Therapists. Control groups also took place on a weekly basis and were made available to participants for an average of 12 months. All lead facilitators had previous experience of working with people with psychosis in groups and all art therapy and activity groups were co-facilitated by another member of staff or volunteer. During the treatment phase of the trial, art therapists and activity group facilitators received local monthly group supervision from senior practitioners with relevant expertise who were not involved in delivering either intervention. Supervision sessions were audio-recorded and recordings reviewed by a senior member of the study team who provided feedback to supervisors regarding adherence to agreed guidelines about the delivery of both interventions. Standard care involved follow-up from secondary-care mental health services, care co-ordination, pharmacotherapy and the option of referral to other services. No restrictions were imposed on referral to other services, apart from arts therapies, which participants agreed not to use until the final follow-up assessment had been completed.

Statistical methods

We calculated that, using a 5% significance level and a design effect of 2.22 (intraclass correlation coefficient = 0.175), we needed data on 300 patients to have 80% power to detect a clinically relevant improvement in GAF score of six points [standard deviation (SD) = 10] between treatments. In anticipation of a 20% dropout rate, we planned to recruit 376 participants.

All primary statistical analyses were conducted using the intention-to-treat principle. Differences in mean score between those randomised to each of the three arms of the trial were examined using analysis of covariance, adjusting for BSL value of the outcome, site, sex and age. A secondary analysis was performed using a multilevel model in order to take into account the clustering effect of the site. In another secondary analysis, we examined the impact of the uptake of the interventions on our primary outcomes using two-stage least squares estimates.

The health economic evaluation was conducted from a broad perspective, covering all health and social services received and productivity losses. Cost-effectiveness was assessed in terms of functioning using the GAF and quality-adjusted life-years using the EQ-5D measure of HRQoL. The cost-effectiveness and cost–utility of the art therapy intervention were explored through the calculation of incremental cost-effectiveness ratios – the difference in mean costs divided by the difference in mean effects. To explore the uncertainty that exists around the estimates of mean costs and effects as a result of sampling variation and uncertainty regarding the maximum cost-effectiveness ratio that a decision-maker would consider acceptable, cost-effectiveness acceptability curves are presented by plotting these probabilities for a range of possible values of the ceiling ratio.

Results

Four hundred and seventeen participants were recruited to the trial between February 2007 and August 2008, of whom 140 were allocated to group art therapy, 140 were allocated to the activity group and 137 to standard care. Participants had a mean age of 41 years (SD = 12 years) and two-thirds ($n = 279$, 67%) were male. Eighty-six (61%) of those randomised to art therapy and 73 (52%) of those randomised to activity control groups attended at least one group. The median delay between randomisation and attending the first group was 61 days for art therapy and 61.5 days for an activity group. Forty-four (31%) of those randomised to group art therapy and 30 (21%) of those randomised to activity groups attended 10 or more groups. The number of participants per art therapy group ranged from zero to six (mean attendance = 2.4, SD = 1.1). The number of participants per activity group ranged from zero to nine (mean attendance = 2.1, SD = 0.9).

No differences in primary outcomes were found between trial arms. The adjusted mean difference between those randomised to art therapy and standard care alone was –0.9 on the GAF Scale [95% confidence interval (CI) = –3.8 to 2.1, $p = 0.57$] and 0.7 on the PANSS Scale (95% CI = –3.1 to 4.6, $p = 0.71$). The adjusted mean difference between those randomised to art therapy and activity groups was –1.1 on the GAF Scale (95% CI = –4.0 to 1.8, $p = 0.47$) and 3.1 on the PANSS Scale (95% CI = –0.7 to 6.9, $p = 0.11$). Differences in secondary outcomes at 12 and 24 months were not found, except that those who were referred to an activity group had fewer positive symptoms of schizophrenia at 24 months compared with those randomised to group art therapy. Instrumental variables analysis indicated that attendance at art therapy groups was not associated with improvements in global functioning or symptoms of schizophrenia.

The mean cost per participant over 24 months was £36,238 for those randomised to group art therapy, £43,795 for those randomised to activity groups and £37,447 for those who received standard care. Although the additional cost of the art and activity group interventions was small compared with the total cost of care provided, we did not find evidence to support the cost-effective use of referring people with schizophrenia to group art therapy.

Conclusions

Levels of attendance at both art therapy and activity groups were low and this may have had an effect on their impact. However, we found no evidence that group art therapy, as delivered in this trial, improves global functioning or health outcomes of people with established schizophrenia or that it constitutes a cost-effective use of resources.

Implications for health care

Although we cannot rule out the possibility that group art therapy benefits a minority of people who are highly motivated to use this treatment, our findings do not provide evidence to support the view that group art therapy leads to improved patient outcomes when offered to most people with schizophrenia.

Recommendations for research

1. Data from exploratory trials of other creative therapies, including music therapy and body movement therapy, have shown promising results and randomised trials examining the clinical effectiveness and cost-effectiveness of offering these interventions to people with schizophrenia should be conducted.
2. Group art therapy has been used as an adjunctive treatment for people with a range of other mental disorders and the impact art therapy for people with these other disorders is also required.
3. The impact of adjunctive art therapy for inpatients with acute psychosis should be evaluated.
4. The impact of adjunctive art therapy and for those with recent-onset schizophrenia should be evaluated.

Trial registration

This trial is registered as ISRCTN 46150447.

Funding

Funding for this study was provided by the NIHR Health Technology Assessment programme and will be published in full in *Health Technology Assessment*; Vol. 16, No. 8. See the HTA programme website for further project information.

Chapter 1

Aims

The study aimed to examine the impact of referral to community-based group art therapy for people with schizophrenia compared with referral to an active control treatment or to standard care alone. We set out to evaluate the impact of referral to group art therapy on health and global functioning and to find out whether or not any benefits associated with art therapy were greater than those associated with referral to an active control treatment. We also sought to compare the costs and cost-effectiveness of adding group art therapy to a person's existing treatment.

The study hypotheses were that among people with schizophrenia:

1. Referral to group art therapy is associated with improved global functioning at 24 months compared with referral to active control treatment or standard care alone.
2. Referral to group art therapy is more cost-effective than referral to active control treatment or standard care alone.
3. Referral to group art therapy is associated with improved mental health, social functioning, well-being and satisfaction with care compared with referral to active control treatment or standard care alone.
4. Those referred to group art therapy will attend a greater proportion of the groups available to them than those referred to active control groups.

Chapter 2

Background

Schizophrenia is a severe mental disorder that affects as many as 1 in 100 people at some point in their lives.[1] In addition to 'positive' symptoms of schizophrenia, such as hallucinations and delusions, many people also experience varying degrees of loss of energy or motivation, impaired attention, reduction in the amount and content of speech and other so-called 'negative' symptoms.[2] Although antipsychotic medication reduces the symptoms of schizophrenia and decreases the likelihood of relapse, it has little impact on negative symptoms of schizophrenia.[3] Previous research has also demonstrated that many people do not adhere to drug treatments and a substantial proportion of those who do continue to experience residual symptoms, relapse and reduced social functioning.[4,5] Psychological and social interventions are widely used in combination with pharmacotherapy in an effort to further improve the health and social outcomes of people with schizophrenia and several have been shown to be effective.[6]

Art therapy is a form of psychotherapy that has been practised for over 60 years.[7] It has been promoted as a means of helping people who may find it difficult to express themselves verbally to engage in psychological treatment. In art therapy, people are provided with a choice of art materials and encouraged to use them to express themselves freely. It has been argued that, for people with psychosis, art therapy has advantages over traditional psychotherapies because the images which a person makes can help a person understand themselves better while containing powerful feelings that might otherwise overwhelm them.[8] The key ingredients of art therapy are considered to be the process of art-making and the relationship that develops between the therapist and the participant.[9] In group art therapy, there is also the potential to explore and utilise the experience of other relationships between group members.[10]

Despite the widespread use of group art therapy for people with schizophrenia, little research has been conducted to explore its effects.[11] Green *et al.*[12] conducted a randomised trial of 10 weekly sessions of group art therapy plus standard care versus standard care alone among 47 people with 'chronic psychiatric disorders', of whom half had a clinical diagnosis of schizophrenia. At 10-week follow-up, those allocated to group art therapy reported improved self-esteem. More recently, Meng *et al.*[13] randomised 86 inpatients to twice-weekly group art therapy delivered over 15 weeks and reported improved health and social functioning at the end of this period . Finally, Richardson *et al.*[14] compared the addition of 12 weekly sessions of group art therapy with standard care among people with chronic schizophrenia who were being treated in outpatient settings. Among 40 (45%) participants who were followed up at 6 months, a statistically significant reduction in negative symptoms was found. Reductions in negative symptoms of schizophrenia have also been reported in exploratory trials of other creative therapies.[15,16] In 2009, national guidelines on the treatment of schizophrenia in England and Wales stated that, given these promising findings, and the relatively poor response that antipsychotic medication makes to negative symptoms of schizophrenia, clinicians should 'consider offering arts therapies to all people with schizophrenia, particularly for the alleviation of negative symptoms'.[17]

However, in their systematic review of the effectiveness of art therapy for people with schizophrenia, Ruddy and Milnes[18] concluded that because of small sample sizes, short follow-up periods and high rates of loss to follow-up, the benefits and potential harms of art therapy

for people with schizophrenia were still unclear. Moreover, because previous studies have not incorporated active control groups there is no evidence regarding the relative contribution of non-specific components and 'active ingredients' of the intervention to observed outcomes, nor has previous research examined the costs or cost-effectiveness of this intervention.

Chapter 3

Methods

The MATISSE (Multicentre evaluation of Art Therapy In Schizophrenia: Systematic Evaluation) study was a three-arm, parallel-group, pragmatic, randomised controlled trial (RCT) of group art therapy plus standard care, control 'activity' group plus standard care or standard care alone. We used a pragmatic design that would allow us to test the impact of referring people to group art therapy in normal clinical practice.

Three changes were made to the design of the study after commencement. First, because recruitment was slower than anticipated, the period for recruiting, the study sample was increased from 9 to 20 months. Second, following publication of national guidance on the treatment of schizophrenia highlighting the importance of arts therapies for people with residual symptoms of schizophrenia,[17] we promoted total symptom score as a co-primary outcome measure alongside Global Assessment of Functioning (GAF) Scale. Finally, early data demonstrating lower levels of attendance at groups than we anticipated led us to increase the total number of participants to 10% above our original target. Ethical approval for the study, including these protocol amendments, was given by Huntingdon Research Ethics Committee (06/Q0104/82) and the study protocol was registered with Controlled Clinical Trials (ISRCTN46150447) prior to the start of data collection.

Study setting and sample

Study participants were recruited from four UK centres: three in England (west London, north London, and Avon and Wiltshire) and one in Northern Ireland (Belfast). Centres were selected because they had systems for delivering group art therapy to people with schizophrenia, and for supervising and supporting arts therapists. The centres included a mix of inner city, urban, semirural and rural areas, and served a population that included people from a variety of different ethnic backgrounds.

We recruited participants from secondary-care settings, including day hospitals, community mental health teams, rehabilitation services, supported accommodation and day centres. Although we identified and assessed potential participants from among those admitted to inpatient mental health units, randomisation did not take place until the person had been discharged from hospital.

To take part in the study, at the point of randomisation potential participants had to be aged 18 years or over, living in the community and have a clinical diagnosis of schizophrenia, confirmed by an examination of case notes using operationalised criteria (OPCRIT).[19] Exclusion criteria were minimised to increase the external validity of study findings. We excluded those who were unwilling to provide written informed consent, those with severe cognitive impairment and those unable to speak sufficient English to complete the baseline (BSL) assessment. People who were currently receiving art therapy or another of the arts therapies (music, dance and movement or drama therapy) were excluded from the study, but those using other forms of structured psychosocial intervention were included.

Study interventions

The MATISSE trial had three treatment conditions: referral to group art therapy plus standard care; referral to an activity group plus standard care; and standard care alone. Owing to limited capacity to take new members into existing groups, new art therapy and activity groups were set up specifically for study participants at each study centre. A total of 15 art therapy and 15 activity groups were set up, to which between 7 and 13 people were referred. The guidance given to group facilitators on processes and response to adverse events of art therapy and activity groups used in the trial is summarised in *Appendices 1* and *2*.

Group art therapy

Those randomised to group art therapy were offered weekly sessions of 90 minutes' duration for an average period of 12 months (and never < 9 months). We planned that no group would have more than eight members, although more than eight people were sometimes referred when those allocated did not engage (see *Table 2*). All groups were led by art therapists who had previous experience of working with people with psychosis and were registered with the Health Professions Council. Groups were co-facilitated by another member of staff or a volunteer.

Group art therapy was conducted in keeping with recommendations of the British Association of Art Therapists.[20] The key ingredients of group art therapy are considered to be the process of art-making and the tripartite relationship, which involves therapist, participant and image.[9] The groups aimed to give people the potential to explore and utilise the experience of other relationships between group members.[10] A range of art materials were available in each group and participants were encouraged to use them to express themselves freely and spontaneously. Relationships within the group were considered in relation to both conscious and unconscious processes. Art therapists generally adopted a supportive approach, offering empathy and encouragement. They rarely provided symbolic interpretations of interpersonal process or images to participants. However, they did frequently discuss these processes in supervision. Within this framework, therapists used a range of interventions thought appropriate to each participant. This approach is in keeping with recommendations for the pragmatic evaluation of complex interventions[21] in which individual therapists are encouraged to apply treatment principles flexibly to fit with the needs of participants.[22]

Activity groups

Activity groups were designed to control for the non-specific effects of group art therapy, identified as structured time with an empathic professional and opportunities for interaction with peers in a group setting. They were also designed to reflect the kind of activity-based groups currently provided by mental health and social care services for people with psychosis in the UK. Allocated participants were offered a place in a weekly activity group of up to 90 minutes' duration for an average of 12 months (and a minimum of 9 months). No group had more than eight members, although more than eight people could be referred to a group to support membership up to this level. All lead facilitators had previous experience of working with people with psychosis in groups and all groups were co-facilitated by another member of staff or volunteer.

Group facilitators offered various activities to members and encouraged participants to collectively select activities for the group. Activities included themed discussion, board games, watching and discussing DVDs, visits to local cafés and occasional visits to places of interest. The use of art and craft materials was prohibited. Group facilitators were asked to refrain from exploring the thoughts and feelings of study participants or offering psychotherapeutic interventions. Where necessary, if, for example, participants became distressed or wanted to

discuss their mental health, facilitators used diversion and/or encouraged participants to take up any specific concerns with professionals already involved in their care.

Prior to entry into groups, art therapists and activity group facilitators met participants individually or in small groups to provide information about the group and promote engagement. Telephone and postal contact with participants and those involved in their care was used to promote engagement and retention in groups.

Standard care

Standard care involved follow-up by secondary-care mental health services, care co-ordination, pharmacotherapy and the option of referral to other services. No restrictions were imposed on referral to other services apart from arts therapies, which participants agreed not to use until the final follow-up assessment had been completed.

Treatment fidelity

All art therapists and facilitators of activity groups attended an orientation meeting at the start of the study. The background and methods of the project were presented and general principles for facilitating groups, arrangements for supervision, and the role of study pro formas were discussed and agreed. During the treatment phase of the trial, art therapists and activity group facilitators received local monthly group supervision from a relevant senior practitioner who was not involved in delivering either intervention in the trial.

Facilitators of all art therapy and activity groups completed a short pro forma at the end of each group. The form required the facilitator to record the structure and content of the group, including the names and number attending and duration of attendance, any breaches of group boundaries and how these were addressed, and the verbal content of sessions and responses made by group facilitators to verbal content. For art therapy groups, therapists were also asked to record the art materials made available and used by the group, and activity groups the facilitators were asked to record the principal activities pursued.

Art therapists were supervised by a senior art therapist and activity group facilitators were supervised by a senior practitioner with relevant expertise. Supervision sessions were audio-recorded and recordings reviewed by a senior member of the study team, who provided feedback to supervisors regarding adherence to general guidelines as presented in *Appendices 1* and *2*.

At the end of the treatment phase of the study pro formas from all centres were collected by the research team and a random sample of 50 (25 from art therapy groups and 25 from activity groups) per study centre (i.e. 200 in total) were examined for treatment fidelity. Data on the verbal content of sessions and responses made by group facilitators were extracted. Specific references to the type of group were removed and a senior member of the study team (MC, HK, DO or TS), masked from the type of group from which data were extracted, rated each as coming from either an art therapy group or an activity group.

Outcome measures

At BSL, demographic and clinical data were collected including age; sex; ethnicity; highest level of educational achievement; employment status; housing status; date of onset of schizophrenia; primary and any secondary clinical diagnosis; current medication; and previous use of structured psychosocial interventions including arts therapies. Written records and in some

cases collateral information gathered from carers or health professions were used to generate a psychiatric diagnosis using OPCRIT.[19] Primary and secondary outcome measures are listed below. Each measure was assessed at recruitment (BSL) and at 1- and 2-year follow-up. Measures were completed either by the researcher, the participant or the participant's key worker as indicated below.

Completed by the researcher

1. *Global functioning (co-primary outcome)* was assessed using the GAF Scale, a 100-point single-item, observer-rated scale that rates functioning on a continuum from health to illness (where '0' indicates the lowest and '100 indicates the highest attainable level of function). It is a reliable and valid measure of global functioning that has been widely used in previous studies of people with schizophrenia and is sensitive to change.[23]
2. *Mental health (co-primary outcome)* was assessed using the Positive and Negative Syndrome (PANSS) Scale.[24] This is a 30-item rating scale that is accompanied by a structured interview. It takes approximately 30 minutes to complete, has been widely used to examine changes in symptoms in people with schizophrenia and related psychoses, and includes validated subscales that can be used to examine changes in positive, negative and general symptoms of schizophrenia. Scores on the PANSS Scale range from 30 to 210, with higher scores indicating poorer mental health.
3. *Medication* All medication being prescribed to participants was recorded and concordance assessed using the Morisky Scale, a four-item questionnaire that provides a valid estimate of use of psychotropic medication.[25] A higher score on this scale indicates lower levels of compliance.
4. *Health-related quality of life* was assessed using the European Quality of Life-5 Dimensions (EQ-5D).[26] This is a generic preferenced-based measure for describing and valuing health-related quality of life (HRQoL) assessed in five domains (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) and higher scores indicate a better quality of life.
5. *Resource use* Information about use of services was collected in interview at BSL and at 12- and 24-month follow-up interviews using the Adult Service Use Schedule (AD-SUS), an instrument designed on the basis of previous studies in adult mental health populations.[27,28] At BSL, information covered the previous 12 months. At each of the follow-up interviews, service use since the previous interview was recorded; in this way, the entire period from BSL to final follow-up was covered. The AD-SUS asks participants for the number and duration of contacts with various services and professionals over the previous 12 months or since the last interview. The 12-month period between interviews meant that there may have been questions over the accuracy of participant recall. In order to increase accuracy and completeness of the data collected, inpatient psychiatric admissions, known to be a key cost driver in this population,[29] were collected from clinical records. Data on attendance at the art and activity groups were collected from therapist records to avoid unmasking of the research assessors.

Completed by the participant

6. Social function was assessed using the Social Function Questionnaire (SFQ),[30] a widely used self-completed measure of social function with established reliability and validity. Scores on the SFQ range from 0 to 24, with '24' indicating poorer social functioning.
7. Well-being was assessed using the General Well-Being Scale. This 18-item, self-report instrument was originally developed for the US Health and Nutrition Survey, but has subsequently been used in studies of people with schizophrenia and has good psychometric properties.[31] Scores on the General Well-Being Scale range from 0 to 110, with lower scores indicating lower levels of well-being.

8. Satisfaction with mental health services was assessed using the Client Satisfaction Questionnaire (CSQ), an eight-item measure that has been widely used in previous studies and is sensitive to change.[32] Scores on the CSQ range from 0 to 32, with higher scores indicating higher levels of satisfaction with care.

Completed by the participants' key worker

9. Engagement with mental health services was assessed using the four-item Service Engagement Scale (SES).[33] Scores on the SES range from 0 to 16, with higher scores indicating greater levels of engagement and acceptance of treatment.
10. Data on occupational and housing status were gathered, indicating whether the participant lived in independent or supported accommodation (and the degree of support provided), together with a short description of any paid work, voluntary work or educational/training activities undertaken by the participant during the previous 6 months.
11. Any incidents of suicidal behaviour, violence or aggression in the previous year were recorded using a pro forma based on the one used by Johnson *et al.*[34]
12. Global functioning was measured using the GAF Scale,[23] rated from the perspective of the lead mental health professional involved in providing mental health services to the patient.
13. Following the collection of all of the 24-month follow-up data, participants' electronic and written records were examined to obtain details of any period of inpatient treatment received during the previous 2 years.

Study procedures

Preparatory phase

During the preparatory phase of the project, researchers were inducted. This involved ensuring they were familiar with study procedures and trained in the use of study outcome measures. Training in the use of the primary outcome measures (GAF and PANSS Scales) was carried out by HK and TB.

Following initial meetings of the Trial Steering Group and Patient Reference Group, we made minor changes to the study protocol, as detailed at the beginning of this chapter.

Recruitment

In each centre, researchers publicised the study through meetings with staff at local inpatient units, community teams, day centres, and rehabilitation and residential units. Researchers visited these teams on a regular basis to promote referral of potential participants. Researchers were assisted in this by clinical studies officers of the UK Mental Health Research Network. Clinical staff were given a copy of an information sheet, which summarised the study protocol and provided details of eligibility criteria. Researchers met those who gave verbal consent to be contacted about the study, assessed eligibility, provided written and verbal information, obtained written consent and collected BSL data.

Randomisation

Participants were randomised via an independent remote telephone randomisation service provided by the Aberdeen Clinical Trials Unit, University of Aberdeen, Foresterhill, Aberdeen. We used permuted stacked blocks, stratified by site. The block size was randomly assigned between 3 and 6. Each element within the block was randomly assigned to one of the three treatments in proportion to the size of the block. Equal numbers were assigned to each of the three arms of the trial.

Participants, their key worker and their general practitioner (GP) were notified of allocation status by an independent administrator. The administrator simultaneously informed the relevant art therapist or activity group facilitator of the allocation status of each participant, so that arrangements could be made for them to receive their allocated intervention. Researchers involved in collecting follow-up data remained masked.

Masking of raters

Rater masking was maintained by providing specific instructions to participants and their clinical teams not to disclose allocation status to researchers carrying out the follow-up interviews. In addition, data were held securely and password protected, had all personal identifiers removed, and randomisation details were held separately and were not accessible to the researchers. Data on participants' uptake of the trial interventions were monitored through pro formas completed by group facilitators after each group, as described above. Thus, researchers did not have to record this information from case files, as this would have led to unmasking.

Participant honoraria

Participants completing follow-up interviews were offered a £15 honorarium in recognition of their time in completing research interviews and any inconvenience related to their involvement in the study.

Sample size

The sample size calculation for the study was based on the primary hypothesis that those randomised to group art therapy will have improved global functioning at 24 months compared with those randomised to active control treatment or standard care alone. At the time the trial was planned, there were no published reports of randomised trials of art therapy for people with schizophrenia in which global function had been assessed; thus, data on mean GAF scores and standard deviations (SDs) were taken from previous trials of compliance therapy and cognitive therapy for people with schizophrenia. These interventions demonstrated an improvement in GAF scores of between 5 and 10 points.[35,36] We powered this trial to be able to detect a difference in GAF score of six points. To detect a mean difference in global functioning of six points on the GAF Scale (SD = 10.0) at 24 months with a two-sided significance level (α) of 5% and power of 80% would require 45 patients in each arm of the trial. In trials of complex interventions there is likely to be clustering of the intervention effect within therapists. In our trial of music therapy for people with schizophrenia, we observed an intraclass correlation coefficient (ICC) of 0.125.[15] However, we anticipated that group processes may lead to a greater clustering of effects and decided to use an ICC of 0.175 for this trial. With an estimated cluster size of eight and an ICC of 0.175, the design effect for the trial was 2.22 and a sample size of 100 per group was therefore required. A sample of 100 participants in each of the three arms of the trial would be sufficient to detect a difference of 50% in mean costs, at the 5% level of significance and with 80% power. In anticipation of a 20% loss to follow-up at 24 months, we planned to randomise 376 participants – 94 at each centre.

Statistical analysis

We used the statistical package Stata version 11.0 (StataCorp LP, College Station, TX, USA) for all the statistical analyses. The statistical analysis plan was approved by the Data Monitoring and Ethics Committee prior to the start of data analysis. Participants' characteristics at BSL were described overall and by randomisation arm. The number of participants who dropped out of the trial (death, withdrawal, losses to follow-up) at 12 and 24 months after randomisation

was compared between the treatment arms. We also compared the BSL characteristics of the participants who completed the follow-up (24 months) with the BSL characteristics of those who did not. For the analysis, missing data at BSL were imputed using regression or mean imputation; no imputation was carried out for the follow-up data. All primary analyses were conducted using the intention-to-treat (ITT) principle, i.e. participants were analysed according to the treatment to which they were randomised, regardless of their compliance with it. Differences in the mean score between those randomised to each of the three arms of the trial were examined using analysis of covariance adjusted by (1) site and BSL value of outcome, and (2) site, BSL value of the outcome, sex and age. The assumption of linearity was assessed by analysis of residuals. The primary outcomes were GAF and PANSS scores at 24 months.

We anticipated that there could be clustering of outcomes as a result of patients being assigned to groups facilitated by different therapists in different sites. Such clustering violates the assumption that observed outcomes of individuals are independent and can result in increased standard errors.[37,38] To take this into account, a multilevel model (also known as linear mixed model) was fitted in a sensitivity analysis. Two levels were considered, site level and patient level, by allowing a random effect by site. Multilevel models were adjusted for BSL value, sex and age.

The primary analysis evaluates the effect of the allocation to the treatment arm and does not take into account the level of compliance observed. In a secondary analysis, we used two-stage least squares estimation of average causal effects in models with variable treatment intensity.[39] This analysis is based on instrumental variable methods and assumes that the effect of allocation to treatment has no effect on the outcome if the patient does not receive the treatment. We estimated the benefit per session, assuming benefit to be proportional to the number of sessions attended, and adjusted for site, sex and age.

Economic analysis

The economic evaluation took a broad cost perspective and included all hospital contacts (inpatient, outpatient, accident and emergency), community health and social services (primary care, community mental health services, social services and voluntary sector services), criminal justice services (prisons, police, probation services and the cost of crimes committed) plus productivity losses resulting from time off work due to illness.

All unit costs were for the financial year 2007–8. A summary of unit costs applied is provided in *Appendix 3*. Trust-specific costs for NHS hospital contacts were sourced from *NHS reference costs 2008*[40] and community health and social service costs were taken from national publications.[41] The cost of medications was calculated using the *British National Formulary*.[42] Contacts with criminal justice agencies were costed using national publications and the charges used by professionals for work completed.[43,44] Where necessary, unit costs were inflated to 2007–8 using the Hospital and Community Health Services inflation indices or the Retail Price Index, as appropriate. Costs in the second year were discounted at a rate of 3.5%, as recommended by the National Institute for Health and Clinical Excellence (NICE; 2004), and the rate was varied from 0% to 6% in the sensitivity analysis. Productivity losses were not calculated because < 5% of the participants were employed at BSL or follow-up.

The cost of intervention sessions were estimated using the bottom-up approach set out by the Personal Social Services Research Unit (PSSRU) at the University of Kent.[45] First, the average salary costs were estimated for the art therapists and activity group facilitators using the mid-point from the appropriate Agenda for Change salary scale and adding on costs of employer national insurance and pension contributions. Next, overhead costs were added to reflect the

therapists/facilitators working in a hospital or community setting. Indirect overhead costs included administrative and managerial support costs and capital overhead costs included the cost of office space. Total salary and overhead costs were then divided by the average number of working hours per year, taken from Curtis,[41] to calculate the cost per hour. As well as time in direct contact with groups, art therapists and activity group facilitators spent time preparing for the groups and in non-client-related activities, such as training and administration. We therefore asked each therapist and facilitator to complete a short survey asking how long they spent on these activities in a typical week. The ratio of direct to indirect client contact that resulted from this survey was used to calculate the cost per hour of direct client contact. Art therapists and group facilitators were assisted by co-therapists and facilitators, and their contribution was calculated by assuming that they were paid as unskilled health-care assistants. In many cases the assistants were volunteers or students; however, their contribution has been valued monetarily for the purpose of the economic evaluation as recommended by best practice guidelines[46] and varied to zero in a sensitivity analysis. The cost per participant was calculated as the sum of therapist/facilitator and co-therapist/facilitator time in direct client contact for the duration of the groups, divided by the number per group (eight). We assumed that groups ran for an average of 40 weeks. Costs were apportioned to each participant on the basis of their randomised status, regardless of attendance at group therapies. This approach is appropriate here because the groups had closed entry and because it acknowledges that the resources have effectively been consumed by an individual at the point of allocation to the group and thus cannot be used by anyone else.[47]

Calculation of quality-adjusted life-years

Quality-adjusted life-years (QALYs) were calculated on the basis of the EQ-5D health state classification instrument, which has five domains: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. For each domain the respondent chooses one of three levels of functioning – good to poor. The three levels for each of the five domains are used to define 243 health states.[48] The health states are then given a utility score using responses from a representative sample of adults in the UK.[49] The QALYs in the second year were discounted at a rate of 3.5%, as recommended by NICE.[50] The QALYs were calculated as the area under the curve as defined by the utility values at BSL and at 12 and 24 months' follow-up, and it was assumed that changes in utility score over time followed a linear path.[51] *The QALYs were adjusted for BSL covariates.*

Cost-effectiveness analysis

Differences in the use of services between randomised groups at 12 and 24 months' follow-up are reported descriptively and are not compared statistically to avoid problems associated with multiple testing, and because the focus of the economic evaluation was on cost and cost-effectiveness. Costs and cost-effectiveness were compared in two sets of analyses: (1) art therapy versus standard care and (2) art therapy versus activity groups.

Primary analysis used available case analysis, including those for whom full data at 12 and 24 months were available; there was no imputation of missing service-use observations. Data on the use of hospital services were available for a larger sample and the impact on results of using these costs alone were explored in sensitivity analysis. Initially, standard statistical tests for differences in costs were used. Although costs were not normally distributed, analyses compared the mean costs between groups using the standard Student's *t*-test. Ordinary least squares regression was used for the adjusted analyses and the validity of results was confirmed using bootstrapping.[52] This approach, rather than logarithmic transformation or the use of non-parametric tests, is used in the analysis of cost data because of the need to make inferences about the arithmetic mean.[53] The primary analysis was of total costs over 24 months. Multiple regression was used to adjust for the following prespecified BSL characteristics: site, age, sex and

total costs at BSL. *The BSL covariates were chosen when the statistical plan was written; they were the factors that the clinical members of the research team considered to be the most important.*

Cost-effectiveness and cost–utility of the art therapy intervention were explored through the calculation of incremental cost-effectiveness ratios (ICERs) – the difference in mean costs divided by the difference in mean effects.[54] For the cost-effectiveness analysis, repeat re-sampling (bootstrapping) from the costs and GAF outcome measure were used to generate a distribution of mean costs and effects for each of the two sets of analyses.[55] These distributions were used to calculate the probability that each of the treatments is the optimal choice, subject to a range of possible maximum values (the ceiling ratio, λ) that a decision-maker might be willing to pay for a unit improvement in outcome. To explore the uncertainty that exists around the estimates of mean costs and effects as a result of sampling variation and uncertainty regarding the maximum cost-effectiveness ratio that a decision-maker would consider acceptable, cost-effectiveness acceptability curves (CEACs) are presented by plotting these probabilities for a range of possible values of the ceiling ratio.[56] The same analysis was carried out for the cost–utility analysis using QALYs.

A number of sensitivity analyses were carried out to test the robustness of the assumptions made:

1. The discount rate was varied from 0% to 6%.
2. Hospital costs only were included to increase the sample size to include those with missing AD-SUS data.
3. The cost of art therapy assistants and co-facilitators was changed to zero to test the impact of volunteer time being valued at zero.

Ethical issues

Only those willing to provide written informed consent were included in the study. Participants were free to withdraw from the study at any time without giving reasons why. However, if participants declined to complete a follow-up interview when first approached, the researcher sought verbal consent to contact them again to see if they were willing to be interviewed. Researchers also contacted participants' key clinicians to see if those who had been ambivalent about completing a follow-up interview would be willing to meet the researcher on a subsequent occasion. Participants completing follow-up interviews were offered a £15 honorarium in recognition of their time and any inconvenience related to their involvement in the study.

Ethical approval for the study, including these protocol amendments, was given by Huntingdon Research Ethics Committee (06/Q0104/82).

Chapter 4

Results

Recruitment and randomisation

Study recruitment commenced in February 2007. The rate of recruitment was slower than anticipated. Interviews with front-line staff conducted to explore this suggested that this was the result of several interconnected factors.[53] These included pressure of clinical work, which had intensified following reconfiguration of services. Clinical staff did not view involvement in research as a priority. Moreover, clinicians had concerns about the rationale for the study and the ethical issues it raised. Some considered it unfair to withhold art therapy from people who were interested in receiving it, whereas others reported being unclear about what art therapy involved and whether or not mental health services should be referring people for this treatment.[57] In response to these difficulties, we convened a range of formal and informal meetings with clinical staff to publicise the study and address these concerns. We also increased the number of sites that we recruited from and extended the period of recruitment.

Between February 2007 and the end of August 2008, 649 people were formally assessed for participation in the study. Of these, 417 (64%) were eligible and were randomised. The reasons for non-participation were: not willing to provide consent ($n = 167$, 72%), not having a diagnosis of schizophrenia ($n = 41$, 18%), already receiving an arts therapy at the point of the assessment ($n = 15$, 6%), moderate or severe cognitive impairment ($n = 6$, 3%) and insufficient spoken English to complete the BSL assessment ($n = 3$, 1%). A total of 131 participants were recruited in west London, 115 in north London, 103 in the west of England and 68 in Belfast. Of the 417 people who took part in the study, 140 were allocated to group art therapy, 140 were allocated to the activity group and 137 to standard care.

Reliability of Global Assessment of Functioning Scale ratings

Inter-rater reliability of researcher GAF ratings was assessed during the first year of the study. Researchers independently rated 24 written-case vignettes. Using a two-way mixed-effects model, the ICC was found to be 0.57 [95% confidence interval (CI) 0.41 to 0.74].

Characteristics of the study sample at baseline

The sociodemographic and clinical characteristics of study participants at BSL are presented in *Table 1*. Participants ranged in age from 18 to 72 years and two-thirds ($n = 279$, 67%) were male. Around three-quarters described their ethnicity as white and the remainder reported being from black and minority ethnic groups. The majority were single ($n = 333$, 80%) and had not achieved a higher education degree ($n = 359$, 89%). The median age at the onset of psychiatric illness was 22 years.

The results of BSL assessments are presented in *Table 2*. The mean GAF score at BSL was 45 (range 9 to 77). All study participants were rated as having some degree of impairment, with the majority having moderate impairment and poor mental health. Despite this, participants' mean

TABLE 1 Sociodemographic and clinical characteristics of study participants at BSL

Variable	Standard care, (*N* = 137)	Activity group, (*N* = 140)	Art therapy, (*N* = 140)	Total, (*N* = 417)
Centre, *n* (%)				
West London	44 (32)	43 (31)	44 (31)	131 (31)
North London	38 (28)	38 (27)	39 (28)	115 (28)
West England	33 (24)	35 (25)	35 (25)	103 (25)
Northern Ireland	22 (16)	24 (17)	22 (16)	68 (16)
Sex, *n* (%)				
Males	99 (72)	90 (64)	90 (64)	279 (67)
Females	38 (28)	50 (36)	50 (36)	138 (33)
Age (years), mean (SD)	40 (12)	42 (12)	41 (11)	41 (12)
Ethnicity, *n* (%)				
White British	76 (55)	71 (51)	71 (51)	218 (52)
White other	25 (18)	28 (20)	31 (22)	84 (20)
Asian	8 (6)	12 (9)	8 (6)	28 (7)
Black	27 (20)	26 (19)	30 (21)	83 (20)
Arab/Middle East	1 (1)	3 (2)	0 (0)	4 (1)
Marital status, *n* (%)				
Married/living as	8 (6)	12 (9)	11 (8)	31 (7)
Divorced/separated	9 (7)	21 (15)	17 (12)	47 (11)
Widowed	3 (2)	1 (1)	1 (1)	5 (1)
Single	117 (85)	106 (76)	111 (79)	334 (80)
Education (*n* = 404), *n* (%)				
Degree	18 (14)	15 (11)	12 (9)	45 (11)
A-levels	14 (11)	21 (15)	20 (15)	55 (14)
GCSE	40 (31)	43 (31)	39 (28)	122 (30)
NVQ/vocational training	22 (17)	13 (9)	18 (13)	53 (13)
Nil	35 (27)	46 (33)	48 (35)	129 (32)
Age at onset of psychosis (*n* = 397), median (IQR)	20 (18 to 26)	22 (18 to 29)	23 (19 to 29)	22 (18 to 29)

GCSE, General Certificate of Secondary Education; IQR, interquartile range; NVQ, National Vocational Qualification.

TABLE 2 Baseline scores on main and secondary outcomes in the three treatment groups

Variable	Completed, *n* (%)	Standard care, mean (SD)	Activity group, mean (SD)	Art therapy, mean (SD)	Total, mean (SD)
GAF	417 (100)	44.9 (12.6)	45.0 (12.7)	44.8 (13.1)	44.9 (12.8)
PANSS	411 (99)	72.6 (21.5)	75.3 (22.0)	74.3 (23.7)	74.0 (22.4)
PANSS-positive	413 (100)	17.3 (5.6)	18.2 (6.8)	18.0 (6.9)	17.9 (6.5)
PANSS-negative	415 (100)	18.5 (7.5)	18.7 (7.0)	18.7 (7.1)	18.6 (7.2)
PANSS-general	415 (100)	36.8 (11.3)	37.6 (12.5)	37.6 (12.5)	37.6 (11.9)
Social functioning	365 (88)	8.1 (4.7)	9.0 (4.8)	8.6 (4.2)	8.5 (4.6)
Well-being	395 (95)	64.5 (20.6)	59.1 (19.5)	58.3 (21.1)	60.6 (20.5)
Care satisfaction	379 (91)	19.8 (1.7)	19.6 (2.0)	19.9 (1.6)	19.8 (1.7)
Morisky Score	403 (97)	1.2 (1.3)	1.2 (1.3)	1.0 (1.2)	1.1 (1.3)
Staff-rated GAF	265 (64)	51.6 (16.7)	53.3 (18.2)	51.5 (18.2)	52.1 (17.6)
SES	286 (69)	10.8 (2.7)	11.4 (2.5)	10.9 (2.7)	11.0 (2.9)

self-reported well-being was moderate/good and participants reported being generally satisfied with the care that they received.

Comparison of BSL characteristics across the three study arms indicates that the groups were well balanced.

Flow of participants through the trial

The proportion of participants who dropped out was less than predicted. The CONSORT (Consolidated Standards of Reporting Trials) diagram (*Figure 1*) summarises the assessments completed at each time point: 361 (87%) were followed up at 12 months and 355 (85%) were followed up at 24 months. Seven participants died during the follow-up period: two were in the art therapy arm of the trial, three in the activity group arm and two in the standard care arm of the trial. Four of the seven deaths were from suicide/probable suicide. Three additional serious adverse events were reported, one a near-fatal episode of deliberate self-harm and two involving harm to others. None appeared to be related to the interventions being examined in the study.

Of the 62 (15%) participants who were not followed up at 24 months, 18 (7%) formally withdrew from the study and seven (2%) died. The remainder either could not be traced or did not take up repeated offers to be assessed (6%). The attrition rate was similar across arms, and there was no difference in reasons for attrition (death withdrawal, lost to follow-up). Participants who completed follow-up had BSL characteristics similar to those who did not (*Table 3*). However, the rate of attrition was higher in north London than in other study centres ($p < 0.001$).

Masking of researchers conducting follow-up interviews

Researchers reported 16 occasions when they became aware of a participants' allocation status. On nine occasions this was when clinical staff revealed which arm of the trial the participant was in, and on seven occasions it was when the participants told the researcher to which arm of the trial they had been allocated. When researchers attempted to guess allocation status following completion of the final follow-up interview, approximately half of their guesses were correct ($n = 119$, 48%).

Uptake of allocated treatments

The number and proportion of those allocated to art therapy and activity groups are presented in *Table 4*. The median delay between randomisation and a person attending their first group was 61 days for art therapy and 61.5 days for an activity group. Those allocated to art therapy attended between 0 and 51 groups, whereas those allocated to control groups attended between 0 and 45 groups. Eighty-six (61%) of those randomised to art therapy attended at least one session, compared with 73 (52%) of those randomised to activity groups ($p = 0.11$). Among those who attended one or more groups, median levels of attendance were higher among those randomised to group art therapy (11 for the art therapy compared with five for activity groups, $p = 0.04$). In addition, 44 (31%) of the 140 participants allocated to group art therapy and 30 (21%) of the 140 allocated to activity groups attended 10 or more groups ($p = 0.06$). The number of participants per art therapy group ranged from zero to six (mean attendance = 2.4, SD = 1.1). The number of participants per activity group ranged from zero to nine (mean attendance = 2.1, SD = 0.9).

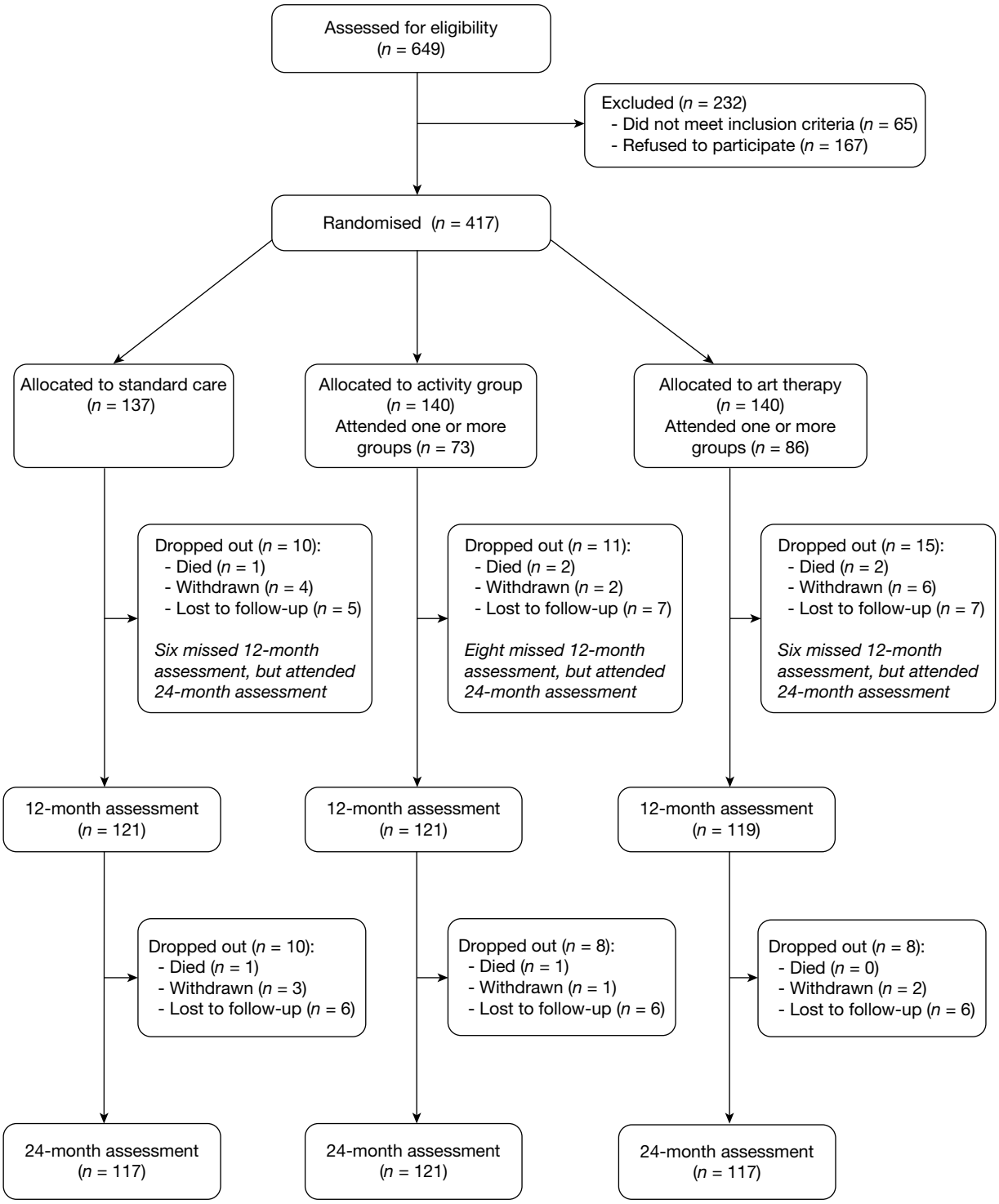

FIGURE 1 Study flow chart.

Two people in the standard treatment arm of the trial and two people randomised to an activity group are known to have attended at least one art or music therapy group. One participant in the standard arm of the trial received 26 sessions of outpatient art therapy and another attended one inpatient music therapy group. One participant randomised to an activity group attended nine sessions of art/music therapy while in an inpatient mental health unit, and another received three sessions of group art therapy while also receiving inpatient treatment. Although all primary

TABLE 3 Baseline characteristics of 355 participants who completed and 62 participants who did not complete the 24 months' assessment [*N* (%), mean ± SD or median (IQR)]

Variable	Completed 24-month follow-up	Did not complete	*p*-value[a]
Study centre			
West London, *n* (%)	118 (33)	13 (21)	< 0.001
North London, *n* (%)	84 (24)	31 (50)	
West England, *n* (%)	93 (26)	10 (16)	
Northern Ireland, *n* (%)	60 (17)	8 (13)	
Sociodemographic characteristics			
Age (years)	41.4 ± 11.2	38.9 ± 12.9	0.11
Sex, *n* (%)			
Females	241 (68)	38 (61)	0.31
Males	114 (32)	24 (39)	
Ethnicity, *n* (%)			
Other	261 (74)	41 (66)	0.23
White	94 (26)	21 (34)	
Marital status, *n* (%)			
Other	281 (79)	53 (85)	0.25
Single	74 (21)	9 (15)	
Education, *n* (%)			
No A-levels	83 (24)	17 (28)	0.54
A-levels or degree	260 (76)	44 (72)	
Psychosis onset age (median), years	22 (18 to 28)	21 (19 to 29)	0.97
Scores on BSL assessments			
GAF	44.9 ± 12.8	44.8 ± 128	0.98
PANSS	73.9 ± 22.2	74.7 ± 23.5	0.81
PANSS-positive	17.8 ± 6.4	18.2 ± 7.2	0.69
PANSS-negative	18.7 ± 7.2	18.5 ± 7.2	0.89
PANSS-general	37.5 ± 11.7	38.0 ± 12.6	0.78
Social functioning	8.5 ± 4.3	8.5 ± 4.6	0.99
Well-being	61.1 ± 20.0	58.0 ± 23.5	0.29
Care satisfaction	24.9 ± 1.8	24.1 ± 1.7	0.67
Morisky Scale	1.06 ± 1.25	1.39 ± 1.46	0.07

IQR, interquartile range.
a The *p*-value from chi-squared test, Student's *t*-test or Mann–Whitney *U*-test, as appropriate.

TABLE 4 Number of sessions attended by 280 participants randomised to art therapy or activity groups

No. of groups attended	Activity group (*N* = 140), *n* (%)	Group art therapy (*N* = 140), *n* (%)
None	67 (48)	54 (39)
One to nine groups	43 (31)	42 (30)
10 or more groups	30 (21)	44 (31)

analyses were based on ITT, the secondary instrumental variables analysis controls for sessions of arts therapies received outside protocol.

Treatment fidelity

A total of 214 pro formas were examined for treatment fidelity. Of these 12 (6%) could not be rated because the pro formas were incomplete. Of the remaining 202 pro formas, 192 (97%) were correctly identified as describing an art therapy or activity group.

Main and secondary outcomes at 12 and 24 months

Baseline and follow-up outcome scores by trial arm are presented in *Table 5*. During the 2-year follow-up period, total symptoms of schizophrenia reduced. Despite this, there was little change in global functioning assessed using the GAF Scale in any of the three arms of the trial.

Mean scores on the GAF Scale among a subsample of participants who completed the BSL, 12- and 24-month follow-up assessment are presented in *Figures 2* and *3*.

Mean scores on the PANSS among those who were rated by the researcher at all three time points are presented in *Figures 4* and *5*.

Table 6 shows the effect of allocation to art therapy (compared with treatment as usual and activity control) on the primary and main secondary outcomes. At 24 months, patients allocated to art therapy showed slightly less improvement in global functioning (GAF) and symptoms reduction (PANSS) than patients in both control arms, but no result was significant. On the secondary outcomes, the results were significant only for the positive symptoms subscale, where patients in the art therapy arm improved significantly less than those in the activity group arm of the trial (adjusted difference 1.3, $p = 0.037$).

Multilevel modelling

Global Assessment of Functioning scores at 24 months showed little clustering across sites (ICC = 0.06), but there was an important variance between site in PANSS scores (ICC = 0.47). When multilevel models were fitted to take account of the clustered structure of the data, the results were very similar to those found in the primary analysis (*Table 7*).

Impact of attendance at groups

The results of the instrumental variables analysis are reported in *Table 8*. The estimated average causal effect of attendance to art therapy for GAF is –0.08 (95% CI –0.35 to 0.19) at 24 months. That is, for every additional session the participant attends we would expect, on average, a drop of 0.08 in the GAF Scale. However, this result is not statistically significant. Similarly, for PANSS score, you would expect, on average, an increase of 0.07 in the PANSS Scale. Again, none was statistically significant.

TABLE 5 Main and secondary outcomes at 12 and 24 months among study participants

	Standard care arm, mean (SD)			Activity groups, mean (SD)			Group art therapy, mean (SD)			Total, mean (SD)		
Outcome measure	BSL	12 months	24 months	BSL	12 months	24 months	BSL	12 months	24 months	BSL	12 months	24 months
GAF	44.9 (12.6)	45.7 (14.4)	46.8 (12.8)	45.0 (12.7)	45.5 (14.1)	46.4 (13.6)	44.8 (13.1)	44.9 (14.6)	45.6 (13.1)	44.9 (12.8)	45.4 (14.3)	46.3 (13.1)
PANSS total	72.6 (21.5)	71.2 (24.6)	68.1 (20.7)	75.3 (22.0)	69.6 (23.2)	66.9 (23.3)	74.3 (23.7)	72.7 (27.3)	69.2 (21.8)	74.0 (22.4)	71.2 (25.0)	68.0 (21.9)
PANSS-positive	17.3 (5.6)	16.7 (6.3)	16.1 (5.5)	18.2 (6.8)	16.1 (5.9)	15.6 (6.4)	18.0 (6.9)	17.3 (7.6)	16.8 (6.5)	17.9 (6.5)	16.7 (6.6)	16.1 (6.2)
PANSS-negative	18.5 (7.5)	18.2 (7.7)	17.2 (7.3)	18.7 (7.0)	17.3 (7.2)	16.4 (6.8)	18.7 (7.1)	18.4 (8.0)	16.9 (7.1)	18.6 (7.2)	17.9 (7.6)	16.8 (7.1)
PANSS-general	36.8 (11.3)	36.3 (13.0)	34.9 (11.3)	37.6 (12.5)	35.9 (12.7)	34.9 (12.4)	37.6 (12.5)	37.0 (14.0)	35.3 (11.4)	37.6 (11.9)	36.4 (13.2)	35.0 (11.7)
Social functioning	8.1 (4.7)	8.5 (4.9)	8.1 (4.8)	9.0 (4.8)	8.1 (4.6)	8.0 (4.5)	8.6 (4.2)	8.3 (5.0)	8.2 (4.8)	8.5 (4.6)	8.3 (4.8)	8.1 (4.7)
Well-being	64.5 (20.6)	64.1 (23.7)	68.1 (18.8)	59.1 (19.5)	63.6 (23.2)	66.1 (18.4)	58.3 (21.1)	59.6 (20.8)	65.1 (18.6)	60.6 (20.5)	62.5 (22.6)	66.4 (18.5)
Satisfaction with care	24.9 (5.7)	24.3 (6.4)	24.2 (5.9)	23.8 (6.2)	25.0 (5.2)	24.9 (5.0)	24.8 (5.7)	23.6 (6.5)	23.1 (5.9)	24.5 (5.9)	24.3 (6.1)	24.1 (5.7)
Morisky Scale	1.2 (1.3)	0.7 (1.1)	0.6 (0.9)	1.2 (1.3)	0.6 (0.9)	0.5 (0.9)	1.0 (1.2)	0.7 (1.0)	0.6 (0.9)	1.1 (1.3)	0.7 (1.0)	0.6 (0.9)
Staff-rated GAF	51.6 (16.7)	49.5 (17.8)	49.5 (16.6)	53.3 (18.2)	50.8 (17.1)	50.6 (15.0)	51.5 (18.2)	50.6 (16.9)	53.5 (14.9)	52.1 (17.6)	50.3 (17.2)	51.1 (15.5)
SES	10.8 (2.7)	10.6 (3.0)	10.0 (2.8)	11.4 (2.5)	10.6 (3.0)	9.8 (2.9)	10.9 (2.7)	10.6 (2.9)	11.3 (2.7)	11.0 (2.6)	10.6 (3.0)	10.3 (2.9)

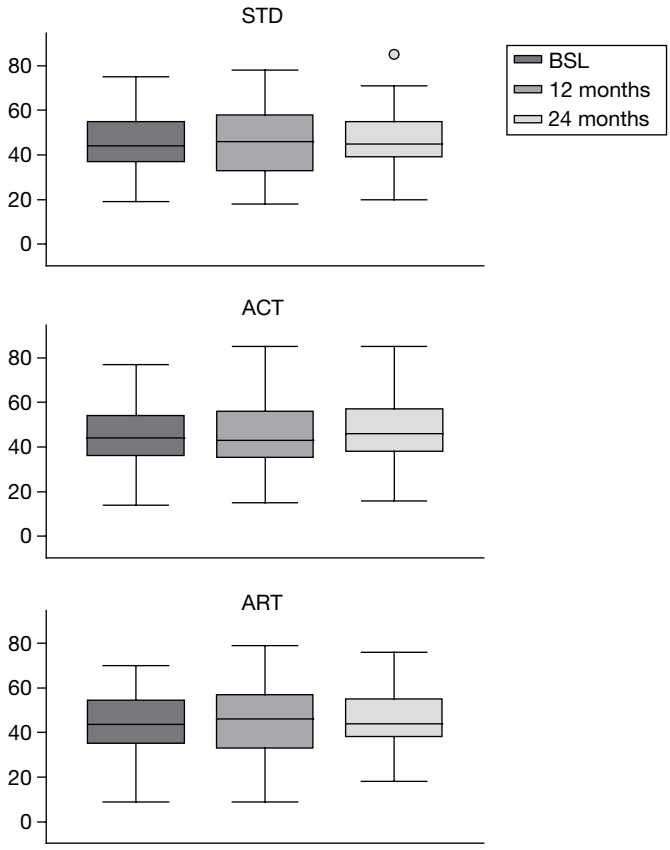

FIGURE 2 Boxplots illustrating mean GAF scores among study participants. ACT, activity group; ART, art therapy; STD, standard care.

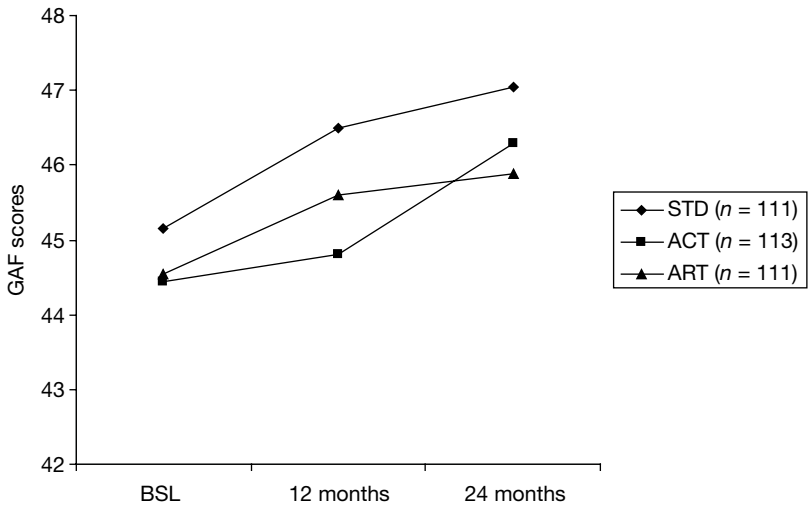

FIGURE 3 Profile plot showing mean GAF scores at BSL, 12 and 24 months in the three trial arms. ACT, activity group; ART, art therapy; STD, standard care.

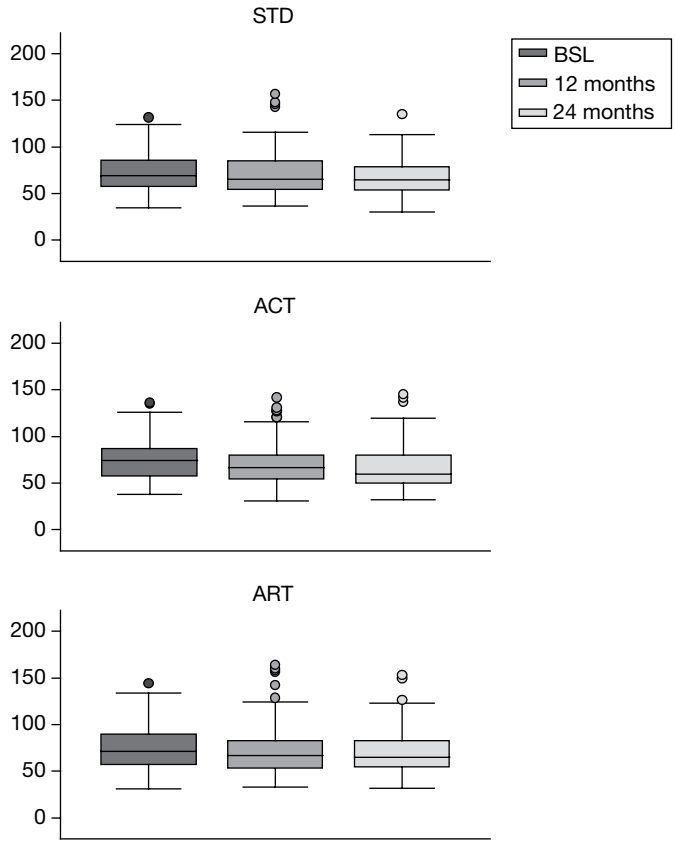

FIGURE 4 Box plots illustrating mean PANSS scores among study participants. ACT, activity group; ART, art therapy; STD, standard care.

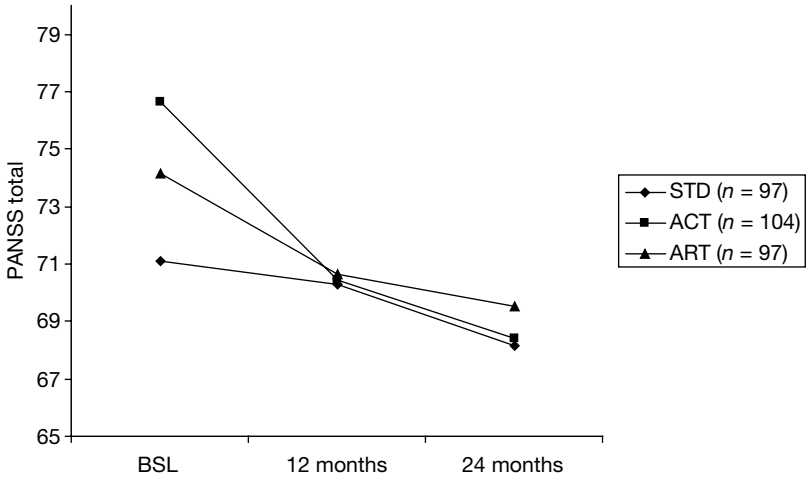

FIGURE 5 Profile plot showing mean PANSS scores at BSL, 12 and 24 months in the three trial arms. ACT, activity group; ART, art therapy; STD, standard care.

TABLE 6 Impact of allocation status on main study outcomes at 24 months

	Adjusted for BSL value and site			Adjusted for BSL value, site, sex and age		
Outcomes	Coefficient	95% CI	*p*-value	Coefficient	95% CI	*p*-value
Primary outcomes						
GAF (n = 355)						
Art vs standard care	–0.9	–3.9 to 2.0	0.53	–0.9	–3.8. to 2.1	0.57
Art vs activity	–1.1	–4.0 to 1.8	0.46	–1.1	–4.0 to 1.8	0.47
PANSS (n = 340)						
Art vs standard care	0.6	–3.2 to 4.5	0.75	0.7	–3.1 to 4.6	0.71
Art vs activity	3.0	–0.7 to 6.8	0.12	3.1	–0.7 to 6.9	0.11
Secondary outcomes						
PANSS-positive symptoms (n = 344)						
Art vs standard care	0.3	–0.9 to 1.6	0.60	0.4	–0.9 to 1.7	0.58
Art vs activity	1.4	0.1 to 2.6	0.03	1.4	0.1 to 2.7	0.03
PANSS-negative symptoms (n = 346)						
Art vs standard care	–0.2	–1.6 to 1.1	0.73	–0.1	–1.5 to 1.2	0.85
Art vs activity	0.8	–0.5 to 2.2	0.24	0.8	–0.5 to 2.2	0.23
PANSS-general symptoms (n = 345)						
Art vs standard care	0.6	–1.5 to 2.6	0.59	0.6	–1.5 to 2.6	0.58
Art vs activity	0.8	–1.2 to 2.8	0.41	0.9	–1.1 to 2.9	0.40

TABLE 7 Impact of allocation status on the main study outcomes at 24 months using a multilevel model

Trial arms	Coefficient	95% CI	*p*-value
GAF (n = 355)			
Art vs standard care	–0.8	–3.7 to 2.1	0.60
Art vs activity	–0.9	–3.8 to 2.0	0.55
PANSS (n = 340)			
Art vs standard care	0.6	–3.2 to 4.5	0.75
Art vs activity	3.1	–0.7 to 6.9	0.11

TABLE 8 Results of instrumental variables analysis at 24-month follow-up, adjusted for site, sex and age

Outcome measure	Effect per session	95% CI	*p*-value
GAF (n = 355)			
Art therapy	–0.08	–0.35 to 0.19	0.55
Activity group	0.02	–0.38 to 0.43	0.91
PANSS (n = 340)			
Art therapy	0.07	–0.28 to 0.42	0.69
Activity group	–0.31	–0.84 to 0.21	0.24

Economic evaluation

The availability of service-use data at each follow-up point is detailed in *Table 9*. Full data were available for almost all randomised cases at BSL (95%). At the 12-month interview, full service-use data were available for around 80% of the sample and at the 24-month interview for around 75% of the sample. Full service-use data for the entire 2-year follow-up were available for 69% of the sample and it is these 286 cases that are included in the base-case analysis. The BSL characteristics of the 286 participants included in the primary analysis and the 131 excluded were very similar and are detailed in *Table 10*.

Service use

The mean number of contacts with each service is detailed by randomised group in *Table 11*. Participants in all groups used staffed accommodation; the mean number of weeks over the 24-month follow-up period was between 33 and 36. Use of hospital services, particularly inpatient care, is high in all groups, although those randomised to the activity group had a higher mean number of nights in hospital than those in the art and standard treatment groups. This difference was a result of more participants in the activity group spending the entire follow-up as inpatients. Use of community services was comparable across the randomised groups, with community mental health services such as community psychiatric nurses (CPNs), home-treatment teams and day and drop-in centres being the most frequently used.

Cost

The total cost of services used is detailed in *Table 12*. At BSL, average costs per participant are highest in those randomised to activity groups; the higher costs are owing to higher rates of inpatient stays in this group and lowest in those randomised to art therapy.

TABLE 9 Availability of service-use data at each follow-up

Assessment period	Standard care ($n=137$)	Activity group ($n=140$)	Art therapy ($n=140$)	Total ($n=417$)
BSL, *n* (%)	131 (96)	133 (95)	132 (94)	396 (95)
12 months, *n* (%)	108 (79)	116 (83)	113 (81)	337 (81)
24 months, *n* (%)	102 (74)	109 (78)	106 (76)	317 (76)
12 + 24 months, *n* (%)	90 (66)	100 (71)	96 (69)	286 (69)

TABLE 10 Baseline characteristics of participants included and excluded from the primary analysis

Variable	Included ($n=286$)	Excluded ($n=131$)
Age (mean, SD)	42 (11)	39 (12)
Sex (proportion male, SD)	0.69 (0.46)	0.62 (0.49)
Ethnicity (proportion white, SD)	0.75 (0.43)	0.66 (0.48)
Marital status (proportion single, SD)	0.78 (0.42)	0.85 (0.35)
Higher education (proportion degree, SD)	0.10 (0.31)	0.13 (0.33)
Total cost (£) for preceding 12 months (mean, SD)	23,432 (26,530)	22,262 (26,263)

TABLE 11 Use of resources 0–24 months' follow-up: mean per participant

	Standard care ($n=90$)		Activity group ($n=100$)		Art therapy ($n=100$)	
Resources	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**
Owner occupied (weeks)	7.3	24.6	10.5	28.5	10.5	28.5
Private rental (weeks)	7.3	24.6	10.5	28.5	10.5	28.5
LA/HA rental (weeks)	46.8	46.1	42.2	46.6	42.2	46.6
B&B (weeks)	0.6	5.5	1.0	10.4	1.0	10.4
Hostel/shelter (weeks)	0.7	5.5	0.0	0.0	0.0	0.0
Rough sleeping (weeks)	0.0	0.0	0.0	0.1	0.0	0.1
Staffed accommodation (weeks)	33.4	43.7	36.3	45.3	36.3	45.3
Inpatient stay (records, nights)	34.5	101.6	64.7	142.6	64.7	142.6
Inpatient stay (self-report, nights)	30.3	97.6	64.8	142.0	64.8	142.0
Outpatient appointments (number)	3.5	6.0	3.2	5.5	3.2	5.5
Accident and emergency (no.)	0.5	1.1	0.2	0.6	0.2	0.6
GP surgery (no.)	9.1	9.4	9.0	10.9	9.0	10.9
GP home (no.)	0.1	1.1	0.1	0.5	0.1	0.5
GP telephone (no.)	1.0	4.8	0.2	0.8	0.2	0.8
Practice nurse (no.)	3.7	6.1	6.4	13.9	6.4	13.9
Case manager (no.)	23.6	31.8	19.9	20.8	19.9	20.8
CPN (no.)	14.3	19.3	22.0	54.2	22.0	54.2
Psychiatrist (no.)	6.3	9.2	4.2	5.7	4.2	5.7
Clinical psychologist (no.)	1.4	4.3	3.0	8.4	3.0	8.4
Home-treatment team (no.)	3.5	13.8	4.4	15.9	4.4	15.9
Crisis resolution team (no.)	12.1	74.7	4.8	21.1	4.8	21.1
Health visitor (no.)	0.1	0.8	0.3	2.8	0.3	2.8
Occupational therapist (no.)	2.4	11.1	5.2	19.2	5.2	19.2
Counsellor (no.)	1.8	7.6	2.8	12.3	2.8	12.3
Family therapist (no.)	0.0	0.0	0.3	1.7	0.3	1.7
Social worker (no.)	5.1	10.9	6.3	17.9	6.3	17.9
Home help (no.)	50.6	125.8	60.3	120.2	60.3	120.2
Day centre (no.)	54.7	99.8	43.3	74.4	43.3	74.4
Drop-in centre (no.)	26.2	45.8	17.8	42.0	17.8	42.0
Drug and alcohol worker (no.)	1.9	10.4	1.8	9.1	1.8	9.1
Advice service (no.)	0.2	0.9	0.2	0.8	0.2	0.8
Helpline (no.)	0.1	0.4	1.7	15.6	1.7	15.6
Self-help (no.)	0.5	4.2	4.4	23.3	4.4	23.3
Prison (nights)	0.7	6.3	0.3	2.8	0.3	2.8
Police custody (nights)	0.1	0.4	0.0	0.2	0.0	0.2
Probation officer (no.)	0.1	0.5	0.1	0.5	0.1	0.5
Police (no.)	0.4	1.3	0.2	0.7	0.2	0.7
Solicitor (no.)	0.4	1.7	0.2	1.1	0.2	1.1
Crimes committed (no.)	0.1	0.3	0.1	0.2	0.1	0.2

B&B, bed and breakfast; CPN, community psychiatric nurse; HA, housing association; LA, local authority.

Mean costs per participant over 24 months' follow-up were highest in those randomised to activity groups (£43,795), followed by standard care (£37,447) and then art therapy (£36,238). Group art therapy and activity groups represent only 2–4% of total costs. The biggest contributor

TABLE 12 Total cost (£) per participant over the 24-month follow-up period

	Standard care ($n=90$)		Activity group ($n=100$)		Art therapy ($n=96$)	
Cost	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**
BSL						
Health and community services	15,349	23,339	18,425	25,602	13,154	20,438
Secondary care	10,516	22,304	13,002	24,262	8364	19,379
Primary care, community	3578	4306	3846	8035	3123	4034
Medication	1256	1817	1577	3527	1667	4302
Accommodation	6379	14,126	6147	10,163	9191	11,624
Criminal justice services	161	1276	278	2236	151	1003
Crimes committed	31	209	60	270	50	439
Total costs	21,921	27,412	24,910	28,083	22,546	23,645
0–12 months						
Health and community services	11,518	18,319	14,274	24,003	9669	16,820
Intervention total cost base case	0	0	445	0	641	0
Secondary care	5751	16,097	8821	22,911	4863	16,378
Primary care and community	4180	5997	3798	6941	2904	3817
Medication	1588	3267	1210	1487	1261	1296
Accommodation	8915	11,617	8106	11,369	8086	11,397
Criminal justice services	53	199	40	252	59	267
Crimes committed	53	278	31	194	17	127
Total costs	20,540	22,830	22,452	25,895	17,830	20,454
0–24 months						
Health and community services	21,115	31,701	26,166	34,757	19,264	28,136
Group therapy	0	0	445	0	641	0
Secondary care	8776	25,885	15,198	33,216	9371	25,990
Primary care and community	9433	17,066	8139	10,266	6607	7400
Medication	2906	4242	2385	2244	2645	2399
Accommodation	16,141	20,775	17,484	21,590	16,675	20,799
Criminal justice services	128	552	106	623	252	1228
Crimes committed	63	303	38	208	47	218
Total costs	37,447	38,694	43,795	42,857	36,238	34,720

to costs was health care (50–60% of total costs) followed by staffed accommodation (35–45%). Costs over time are shown in *Figure 6*. Total costs fall over time in the standard care and activity group arms of the trial groups; for those randomised to group art therapy, there is a greater fall in costs at 12 months but costs then rise again at 24 months.

The difference in costs over 24 months between randomised groups is detailed in *Table 13*. In the art therapy-versus-standard care comparison, the mean difference of £1210 is not significant. In the art therapy-versus-activity group comparison, although there is a mean difference in cost of £7557, it is not statistically significant ($p=0.865$). These comparisons have been adjusted for BSL cost, site, age and sex. *A further analysis using multiple imputation of missing total costs was also carried out, but as this made little difference to the findings it is not reported here.*

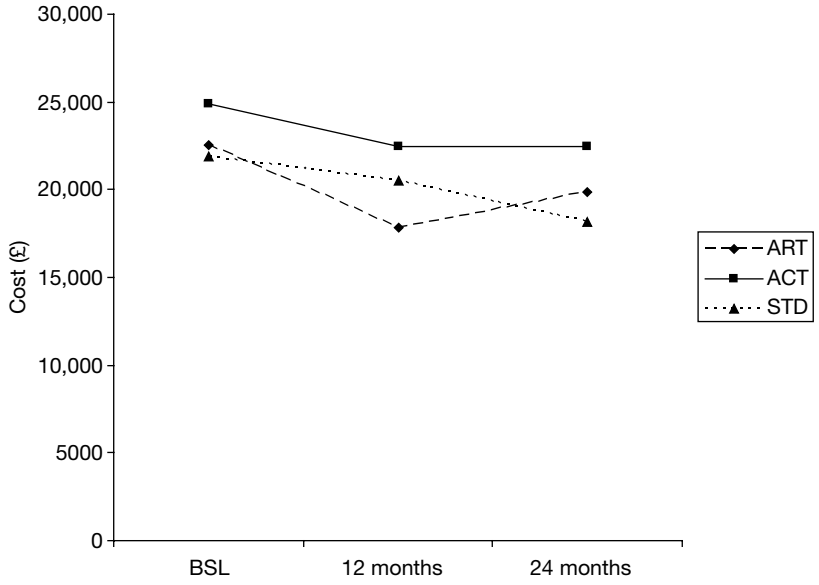

FIGURE 6 Total cost by randomised group over time. ACT, activity group; ART, art therapy; STD, standard care.

Outcomes for the economic evaluation

Quality-adjusted life-years and global functioning over follow-up are detailed in *Table 14*. Mean QALYs were very similar between groups and in years 1 and 2, and changed little over time. There were no significant differences in QALY scores.

Cost-effectiveness

Art therapy versus standard care

Those randomised to art therapy had lower costs and better outcomes than those randomised to standard care: the ICERS were –£1011 per unit change in GAF score and –£28,105 per QALY, which suggest that the art therapy could save money and improve outcomes. However, the ICERs are based on raw, unadjusted mean scores and do not account for uncertainty around costs and outcomes. The adjusted bootstrapped replications for the cost and effectiveness pairs and the CEAC, using GAF scores as the outcome measure, are presented in *Figures 7* and *8*, respectively. *Figure 8* shows that art therapy has at least a 50% probability of being cost-effective compared with standard care, and the probability that it is cost-effective increases if decision-makers are willing to pay increasing amounts for unit improvements in GAF. However, the probability that referral to art therapy is cost-effective never rises above 67% for willingness-to-pay values up to £10,000. For the cost–utility analysis (*Figures 9* and *10*), the CEAC stays very close to 50%, suggesting that the probability that referral to art therapy is cost-effective compared with standard care is no greater than 50% for any value that a decision-maker may be willing to pay for improvements in outcome.

Art therapy versus activity groups

Those randomised to art therapy had lower costs and better outcomes compared with those randomised to activity groups. The ICER was –£15,944 per unit change in GAF score and –£303,793 per unit change in QALY. Scatterplots for both GAF score (*Figure 11*) and QALYs (*Figure 12*) are centred around zero, generating CEACs (*Figures 13* and *14*, respectively) that stay very close to 50%, so the probability that art therapy is cost-effective compared with activity groups is not > 50% for any value that a decision-maker may be willing to pay for improvements in outcome.

TABLE 13 Differences in total costs per participant over the 24-month follow-up period

Comparison	Mean difference	95% CI[a]	*p*-value
Standard care vs art therapy	–1210	–9112 to 8921	0.983
Activity groups vs art therapy	–7557	–9741 to 8283	0.865

a The 95% CI and *p*-value bootstrapped and adjusted for BSL cost, site, age and sex.

TABLE 14 Outcome, mean per participant at 24 months

	Standard care		Activity groups		Art therapy	
Outcome	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**
Quality of life						
BSL utility score ($n=409$)	0.664	0.278	0.664	0.274	0.699	0.268
12-month utility score ($n=357$)	0.643	0.303	0.702	0.306	0.688	0.282
24-month utility score ($n=346$)	0.717	0.214	0.691	0.281	0.747	0.256
QALY over follow-up ($n=317$)	0.665	0.212	0.684	0.237	0.708	0.215
GAF						
Year 1 ($n=361$)	44.90	14.61	45.50	14.06	45.73	14.44
Year 2 ($n=355$)	45.64	13.09	46.36	13.64	46.84	12.77

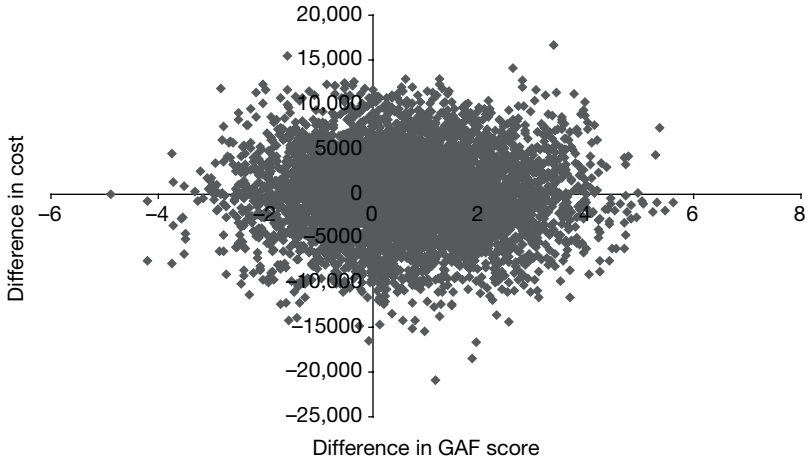

FIGURE 7 Scatterplot showing the bootstrapped mean differences in costs and effects of art therapy and standard care using the GAF score.

Sensitivity analysis

The results of the sensitivity analyses are detailed in *Table 15*. Varying the discount rate from 0% to 6% did not impact on the findings, nor did increasing the sample size by including psychiatric admission costs from records only. When the cost of the group interventions are calculated assuming that all art and activity group assistants are volunteers or students and that the cost of their contribution is zero, there is no impact on the results.

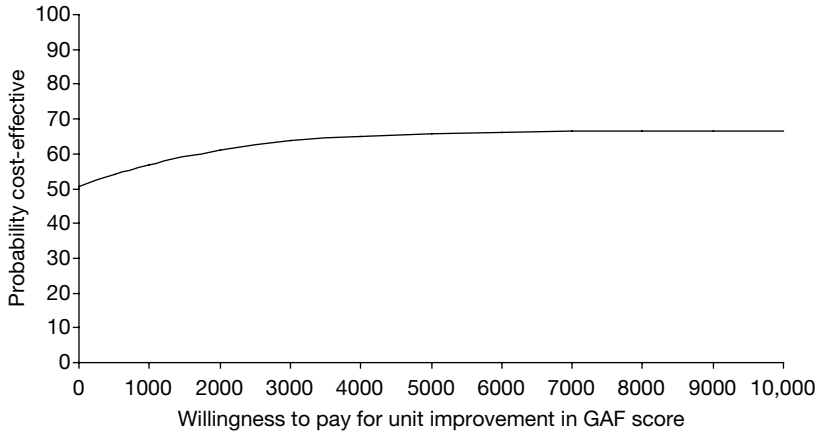

FIGURE 8 Cost-effectiveness acceptability curve showing probability that art therapy is cost-effective compared with standard care for different values of willingness to pay for improvements in GSF.

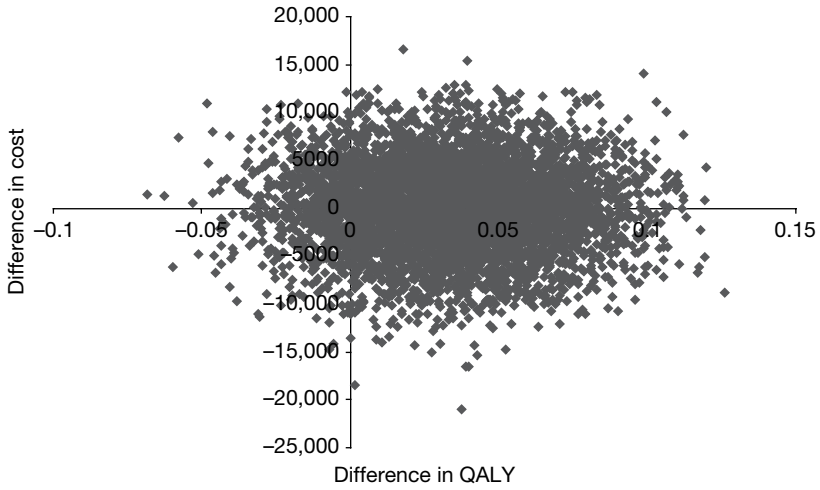

FIGURE 9 Scatterplot showing the bootstrapped mean differences in costs and effects of art therapy and standard care using QALYs.

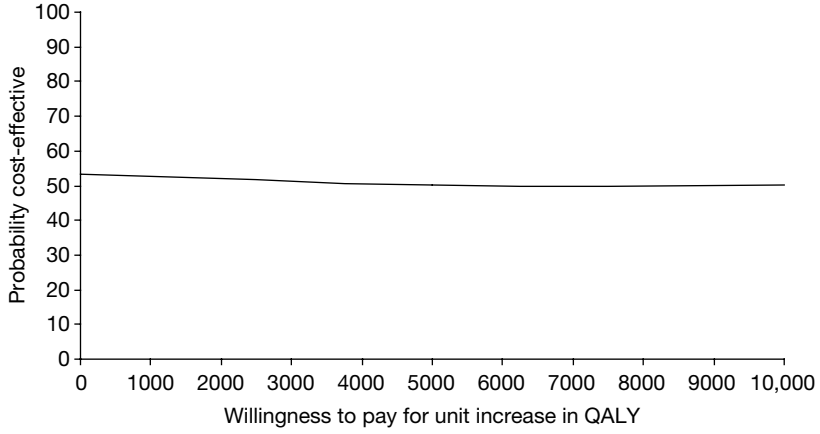

FIGURE 10 Cost-effectiveness acceptability curve showing probability that art therapy is cost-effective compared with standard care for different values a decision-maker may be willing to pay per QALY.

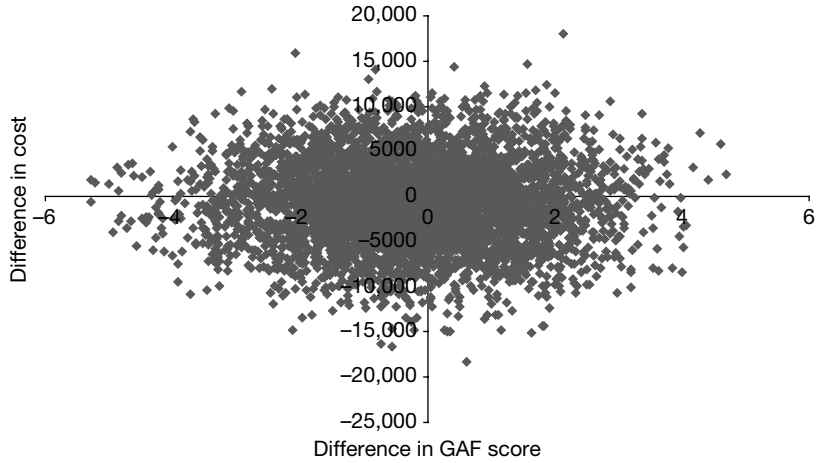

FIGURE 11 Scatterplot showing the bootstrapped mean differences in costs and effects of art therapy and activity groups using GAF score.

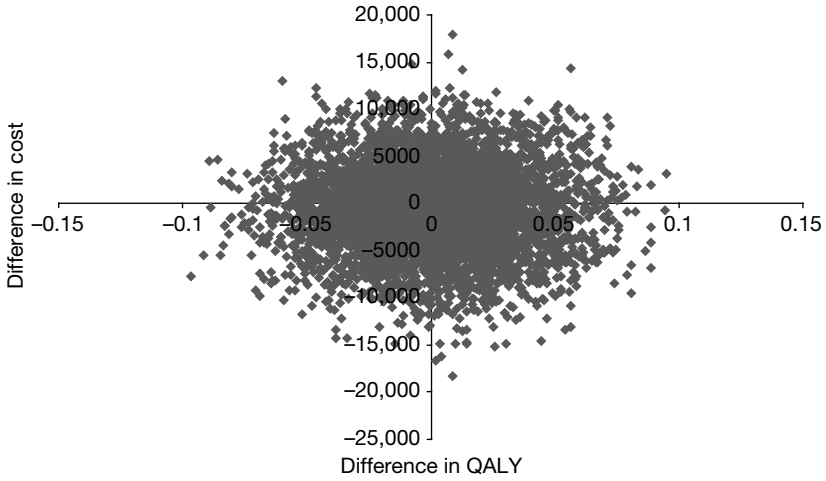

FIGURE 12 Scatterplot showing the bootstrapped mean differences in costs and effects of art therapy and activity groups using QALYs.

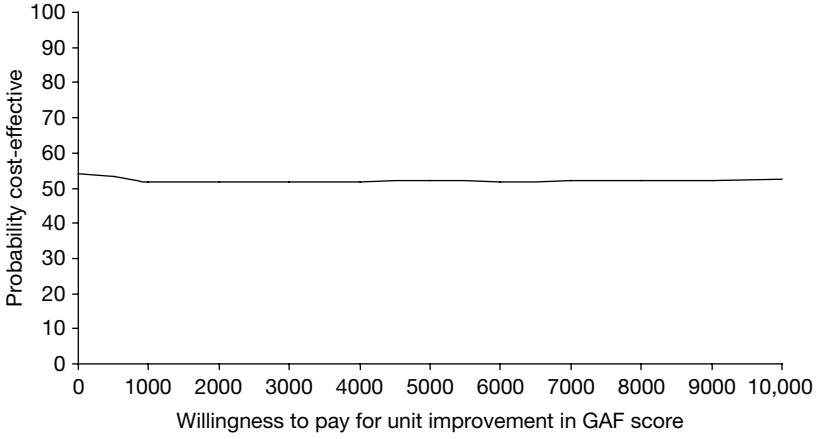

FIGURE 13 Cost-effectiveness acceptability curve showing probability that art therapy is cost-effective compared with activity groups for different values of willingness to pay for improvements in GAF.

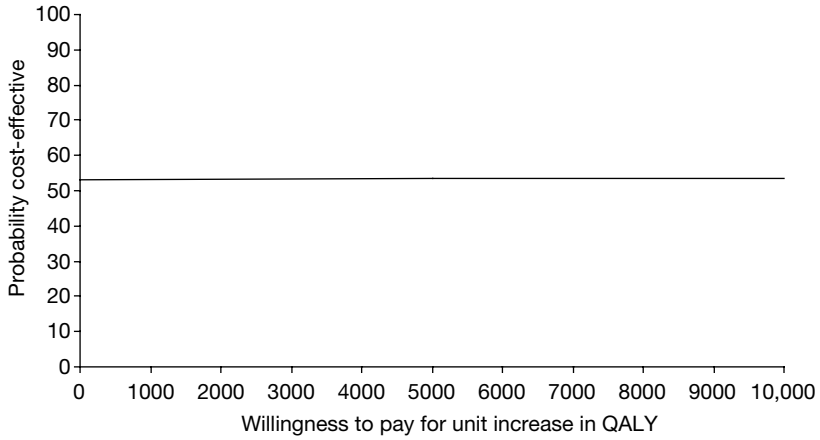

FIGURE 14 Cost-effectiveness acceptability curve showing probability that art therapy is cost-effective compared with activity groups (ACTs) for different values of willingness to pay per QALY.

TABLE 15 Sensitivity analyses for total cost (£) per participant over the 24-month follow-up period

	Standard care		Activity group		Art therapy		Art therapy compared with standard care			Art therapy compared with activity groups		
Analysis	Mean	SD	Mean	SD	Mean	SD	Mean difference	95% CI	*p*-value	Mean difference	95% CI	*p*-value
Discount rate 0% ($n=286$)	36,872	39,298	44,554	36,872	36,872	35,353	1140	–9181 to 9173	0.999	7682	–9794 to 8281	0.862
Discount rate 6% ($n=286$)	35,809	38,289	43,283	35,809	35,809	34,296	1258	–9067 to 8751	0.972	7474	–9496 to 8076	0.867
Inpatient costs only ($n=333$)	9283	29,053	15,574	9283	9283	26,550	1048	–3727 to 8969	0.433	6291	–8961 to 4803	0.552
Assistants as volunteers ($n=286$)	36,127	38,694	43,695	36,127	36,127	34,720	1320	–9212 to 8798	0.964	7568	–9158 to 7679	0.863

Chapter 5

Discussion

Study findings

Among a sample of 417 adults diagnosed with schizophrenia receiving standard care from mental health services, those randomised to weekly group art therapy had similar levels of global functioning and mental health as those randomised to an activity control group and those randomised to standard care alone over a 2-year period. However, a greater reduction in positive symptoms of schizophrenia was seen among those randomised to activity groups (compared with art therapy) at 2 years.

Those offered a place in an art therapy group were more likely to attend sessions than those offered a place in an activity group. However, the levels of attendance at both types of group was low, with 39% of those referred to art therapy and 48% of those referred to activity groups not attending any sessions. A secondary analysis of data examining the changes in main study outcomes with group attendance suggested that the two were not related. Group art therapy was estimated to have cost £641 per patient, on average. Other costs among those allocated to group art therapy, control groups and standard care were similar. We did not find that referral to group art therapy was more cost-effective than referral to an activity group or to standard care alone.

These findings differ from those of three previous clinical trials of art therapy that have included people with schizophrenia. However, considerable caution needs to be used when interpreting the results of these previous studies due to various methodological limitations.

In a small trial ($n = 47$) of group art therapy for people with chronic mental illness by Green *et al.*,[12] only half of those included had a diagnosis of schizophrenia. Those randomised to group art therapy were offered 10 weekly sessions of 90 minutes' duration. At each group participants were given predetermined goals. Detailed information about levels of attendance was not provided, but the authors state that, of 19 people who were followed up, eight (42%) attended fewer than three sessions. The authors subsequently compared outcomes between patients who completed all 10 groups and those who did not.

The study by Meng and *et al.*[13] took place on an inpatient unit. A total of 86 people who met diagnostic criteria for schizophrenia were randomised to 15 weeks of twice-weekly group art therapy plus standard care or standard care alone. Group art therapy was delivered by a researcher who set drawing tasks which involved recommending that participants used particular techniques and art materials to make images that illustrated predetermined themes and other 'delegated tasks'. The researcher provided active assistance to participants to help them complete images and suggested which art materials to use. At the end of the sessions the researcher commented on the images made by participants with the aim of helping them develop a better understanding of their problems. Follow-up assessment was conducted at 4 months. The published report does not provide information about levels of attendance at groups or dropout. It is also unclear whether or not the researcher who conducted follow-up assessments was masked to the allocation status of participants or whether reported outcomes were among all those who took part in the trial or only those who completed the treatment.

In the third study, conducted by Richardson *et al.*,[14] 90 people living in the community who had a clinical diagnosis of chronic schizophrenia were randomly allocated to standard care or standard care plus 12 weekly sessions of group art therapy of 90 minutes' duration. A total of 452 patients were assessed for suitability, but four out of five were not included, mainly because they did not complete the BSL assessment or refused to take part in the study. An interactive approach was taken to therapy in which participants were given a range of art materials and encouraged to use these to express themselves freely. Follow-up assessments were conducted at 3 and 6 months, and 82% were reassessed at the first follow-up interview and 44% at the final one. Data on attendance at groups were not provided in the study report, but personal communication with the research team revealed that 37% attended no sessions, 16% attended 10 or more sessions, and mean attendance was 3.5 (compared with 39% any attendance, 31% 10 or more sessions, and a mean attendance of 9.8 groups in the MATISSE study). The authors of this study acknowledge that unmasking of the researcher conducting follow-up assessments might have occurred, but provide no information about whether or how often this happened.

The MATISSE study differs from previous clinical trials of group art therapy in several important ways. First, it was powered to detect clinically important differences in study outcomes, including cost-effectiveness. Second, we collected and have reported detailed information about attendance at groups. All our main analyses used an ITT approach. We offered group art therapy of a length and duration that is more like that offered in real-life clinical practice. A rigorous approach to keeping researches masked to allocation status was used, and when researchers were told about a participant's allocation status an alternative researcher conducted subsequent interviews.

In keeping with recommendations for pragmatic trials, we did not aim to control the content of individual art therapy sessions.[58,59] Rather we sought to test the impact of group art therapy as delivered in clinical practice. In conjunction with the MATISSE trial, we conducted a national survey of art therapists in England with the aim of establishing whether or not the approach used in the trial was in keeping with that in routine clinical practice.[60] The results of this survey showed that the non-directive, art-focused approach used by therapists in the MATISSE study is consistent with that provided by art therapists across mental health services in England. Similarly, art therapists both in the MATISSE study and in the NHS in England consider interactions among the therapist, the patient and members of the group in psychodynamic terms, but rarely use explicit interpretations of the content of images or group processes. We, therefore, believe that the approach to group art therapy used by therapists in the MATISSE study is broadly representative of that used more generally within the NHS.

The MATISSE study used a robust design, which was developed to specifically address the limitations of previous studies of art therapy for people with schizophrenia. However, the MATISSE study also had limitations that need to be considered when interpreting the study findings.

Study limitations

Almost 40% of those participants randomised to group art therapy and over half of those randomised to activity groups did not attend any sessions. Among those who did, very few attended regularly. Attendance at group art therapy was also low in previous community-based studies among people with psychosis,[12,14] and the mean number of sessions attended in these two trials was lower than that found in the MATISSE trial. Possible explanations for the low level of attendance are that the interventions may not have been acceptable to participants or that participants lacked the motivation and organisational skills to attend.[61] Usual practice in the NHS is that art therapists meet with patients to talk to them about what therapy involves and

assess their degree of interest and motivation to attend before offering them a place in a group. By focusing on delivering art therapy to people who are more motivated to attend, overall levels of attendance are likely to be higher in clinical practice than has been reported in clinical trials.[56]

Many groups had only one or two regular attendees, and the average attendance at art therapy groups was between two and three people. Although this meant that therapists may have been able to pay greater attention to each person who attended than if groups had been larger, it also made it difficult for therapists to make use of group interaction, which is considered to be an important therapeutic element of group art therapy.[62] Opportunities for group members to interact with each other and model the interactions of the therapist were therefore likely to have been limited. The inconsistent attendance of many group members could also have reduced group cohesion and made it more difficult for group members to feel safe enough to discuss difficult or sensitive matters. Although we designed the study such that new participants could enter a group when it was clear that another member would not attend, the relatively small size of groups and inconsistent patterns of attendance may have limited their potential to improve patient outcomes.

We deliberately set out to recruit a representative sample of those with schizophrenia rather than a self-selected subgroup of those who wanted art therapy. Although all of those whom we recruited indicated a willingness to attend and therapists made concerted efforts to engage people in groups, many of those in the study did not do so. Levels of attendance at group art therapy and activity groups were lower than has been reported in studies of other types of group-based interventions.[63,64] During the course of the study we found that many of those working in general mental health services were unsure about whether or how group art therapy could help patients.[57] It is thus possible that those working in these settings did not provide the level of support and encouragement to attend group art therapy that they would for cognitive behavioural therapy and other psychological interventions, and that this also contributed to the low level of attendance at groups.

Although our instrumental variables analysis found no association between participants' attendance at groups and the primary study outcomes, our analysis was limited in assuming a linear relationship between the number of sessions and treatment effect. Although we believed this approach minimised assumptions about an effective dose of treatment, the cumulative approach to treatment effect it uses is naive and could miss important thresholds that patients have to cross in terms of therapeutic dose.

We did not collect outcome data during the intervention phase of the study. Instead, we collected data at the end of the intervention phase (12 months after randomisation) and 12 months later (24 months after randomisation). Although it is possible that shorter-term benefits of the intervention have been missed, the absence of statistically or clinically significant differences in outcomes between participants in the three intervention arms at 12 months suggests that, even if shorter-term benefits did occur, these were no longer present at 1 year.

Inter-rater reliability among researchers involved in the study was not high. It is generally agreed that ICCs of between 0.41 and 0.6 indicate a 'moderate' level of agreement and that scores >0.61 indicate a 'good' level of agreement.[65] However, inter-rater reliability was based on short vignettes rather than the more detailed picture obtained by researchers during the study. Previous research examining inter-rater reliability of the GAF Scale has generally demonstrated higher levels of inter-rater reliability among trained researchers when assessing patients during clinical interviews,[66] but lower levels of agreement among clinical staff have generally been reported.[66,67] It is possible that inter-rater reliability would have been higher if researchers had been given a more detailed clinical description, which included information from clinical staff in the vignettes.

All researchers were trained in the use of the GAF Scale and discussed ratings with their supervisors. The main advantage of the GAF Scale is that it provides a simple global measure that incorporates elements of both health and social functioning. However, in trying to combine these different elements it can be difficult to accurately rate those whose social functioning is poor while mental health is stable or vice versa.[67,68] Although it is possible that the GAF Scale did not provide an accurate measure of global functioning in this study, it is of note that none of the other standardised measures that we used to assess other outcomes identified any clinical benefit of group art therapy over activity groups or standard care alone either.

Previous accounts of the potential benefits of art therapy and feedback from service users to whom we presented our initial findings suggest that art therapy may help people in ways that are difficult to quantitate. Although we used a broad range of outcome measures that included widely used assessments of health and social functioning as well as well-being and satisfaction with care, we do not know whether art therapy resulted in other outcomes that are valued by service users but which were not measured in this trial.

Implications for health care

Although we cannot rule out the possibility that group art therapy benefits people with schizophrenia who are motivated to use this treatment, our findings suggest that it does not lead to improved patient outcomes and is not a cost-effective use of resources when offered to most people with this disorder. This finding suggests that group art therapy should not be offered on a broad basis to all patients with this disorder, but that a preliminary assessment of a patient's interest and motivation to attend sessions should be made so that it can be targeted at those most likely to make use of it.

The possibility that the lack of clinical improvement among participants in this trial may simply reflect the high degree to which people with established schizophrenia are impaired in their clinical and social functioning must be considered. These impairments are known to increase over time.[69] The mean length of illness among the study population was 17 years. Targeting interventions at an earlier stage of the illness may be more effective. Other psychosocial interventions such as cognitive behavioural therapy and family psychoeducation have been shown to improve health and social functioning in this group. However, it may be that to benefit from group art therapy patients need a greater capacity for reflective and flexible thinking than that which these more structured interventions require.

Recommendations for research

Guidance on the treatment of people with schizophrenia has sometimes discussed art therapy in combination with other creative therapies, including music therapy, drama therapy and body movement therapy.[70] However, the purpose and purported active ingredients of these therapies differ and data from exploratory trials of other creative therapies are promising.[15] These creative therapies may stimulate other cognitive processes and lend themselves to greater levels of interaction with therapists and other group members. Randomised trials examining the clinical effectiveness and cost-effectiveness of offering these interventions to people with schizophrenia should be conducted. However, before large-scale definitive trials of such interventions are started, it is essential that high-quality pilot trials are completed, which provide a clear estimate of uptake and engagement in these treatments.

Most participants in the MATISSE study had received treatment for schizophrenia over a number of years. It has been argued that early intervention for people with schizophrenia in the initial period after the first onset of symptoms may provide a more effective means of reducing social and interpersonal problems.[71,72] Although we did not find evidence that referral to group art therapy among those with established psychosis led to improvements in mental health or global functioning, it is possible that group art therapy delivered at an earlier stage in disorder has beneficial effects. The impact of group art therapy with recent onset of psychosis should be evaluated.

Major concerns have been expressed about the treatment of inpatients with acute psychosis. Group art therapy is often delivered to inpatients and levels of attendance at groups may be higher in this setting. The single clinical trial of group art therapy for people with schizophrenia delivered to inpatients demonstrated promising findings[13] and further investigation of the clinical effectiveness and cost-effectiveness of art therapy for inpatients with schizophrenia is required.

Individual and group art therapy is also used to help people with a range of other mental and physical health problems and the impact of these interventions in other conditions requires further evaluation.

Our experience of setting up new 'closed' groups for research participants in the MATISSE study was that it is difficult to help give people a group experience when few group members have had previous experience of group therapy. For highly structured groups that aim to impart new skills or achieving pre-set objectives this may not present a problem. However, for group-based interventions, such as art therapy, which are far less structured and aim to promote interaction with other group members, there may be advantages in allocating study participants in existing 'slow open' groups in which other group members have already attended the group for some time. Such groups may help to ensure that, at the start of treatment, new participants can benefit from the experience of established group members. We therefore suggest that, where possible, future trials of group-based art therapy and other less-structured group-based therapies use existing 'slow open' groups rather than setting up closed groups specifically for trial participants.

Our finding of a greater reduction in positive symptoms of schizophrenia among those randomised to activity groups compared with those randomised to art therapy was unexpected. Although statistically significant, the difference was small and could be a type 1 error associated with multiple testing. Nonetheless, the impact of activity groups on the mental health and social outcomes of people with schizophrenia should be further evaluated and the data we collected in the MATISSE study provide a valuable opportunity to do this.

Chapter 6

Conclusions

We found that referral of people with schizophrenia to group art therapy did not lead to medium-term improvements in global functioning, mental health symptoms or quality of life. However, attendance at both art therapy and activity groups in the study was low and this may have had an effect on their impact. Although many service users greatly value using art materials and taking part in other creative activities, the widespread referral of people with established schizophrenia to group art therapy as delivered in this study did not lead to measurable improvements in patient outcomes or provide a cost-effective use of resources.

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Contribution of authors

Mike Crawford, Helen Killaspy and Diane Waller were co-principal investigators of the MATISSE trial and were involved in the planning and supervising the conduct of the study.

Eleftheria Kalaitzaki designed the statistical analysis plan with guidance provided by Tony Johnson. Outcome data were analysed by Baptiste Leurent, with guidance from Tony Johnson.

Sarah Byford designed the economic component of the trial, supervised the conduct of the economic evaluation and contributed to the writing of the final report.

Barbara Barrett carried out the cost-effectiveness analysis and contributed to the writing of the final report.

Diane Waller, Katie Clayton and Anna Maratos provided clinical expertise on arts therapies.

Diane Waller and Katie Clayton led the training of art therapists.

David Osborn led the training of activity group facilitators.

The principal investigators at each site were Mike Crawford (west London), Helen Killaspy (north London), Tony Soteriou (west of England), Tony O'Neill (Belfast).

Sue Patterson recruited study participants in west London, Angela Hoadley recruited study participants in north London, Siobhan Floyd recruited study participants in the west of England, and John Dinsmore recruited study participants in Belfast.

Michael King, Tom Barnes and Peter Tyrer provided trial methods expertise, including input to the planning of the study and the data analysis plan.

All study authors contributed to the preparation of this report.

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- West London:
  - *Art therapy* Fiona Foster (supervisor), Kate Emerson, Diane Eagles, Dominik Havsteen-Franklin, Tessa Rawcliffe and Michael Scott (art therapists). Jude Godyer, Sarah Dickenson and Kate Philips (co-facilitators).
  - *Activity groups* Suzie Willis (supervisor), Beth Eynon, Sulzbacher Christine, Lee Buyers and Joe Mursell (group facilitators). Maria Sampson, Sean Logeran, Nell Ellison and Hannah Istead (co-facilitators).
- North London:
  - *Art therapy* Katie Clayton (supervisor), Timothy Duesbury, Andrew Gibson and Kate Malone (group facilitators). Isobel Johnstone and Adam Leven (co-facilitators).
  - *Activity groups* Linda Norton and Rachel Finkel (supervisors), Diana Kagiafa, Koray Djafer, Virginia Lumsden, Deborah Mathews and Jennifer Medlock (group facilitators/ co-facilitators).
- West of England:
  - *Art therapy* Vicky Morrison (supervisor), Marilyn Miller, Sarah Anderton and Sarah Parkinson (art therapists). Joseph Blakey, Felicity O'Sullivan and Susan Lowther (co-facilitators).
  - *Activity groups* Fiona Williams (supervisor), Richard Davey, Odette Morris and Stephen George (group facilitators). Sally Easton, Patricia Kaines, Mark Bernard and Darren Piercy (co-facilitators).
- Belfast:
  - *Art therapists and co-facilitators* Carol Sibbet (supervisor), Margaret Dunlop, Frank Holmes, Brendan O'Neill and Esther Twomey.
  - *Activity groups* Tony O'Neil, Maria O'Kane (supervisor), Janet McCusker, Alan Kilpatrick, Kiera Milligan, Harry Mulholand, Artie Nolan, Alison Rennick and Hugh Scullion (group facilitators and co-facilitators).

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Appendix 1

Group processes and response to adverse events used in the trial

Aspect of structure or content of groups	Aspects shared by art therapy and activity groups
Engaging with the group	Group facilitators should contact new members by post and or telephone to invite them to the group and provide them with details of location, start times, etc. Facilitators should try to meet participants on one occasion before they commence the group to outline aims, protocol boundaries and expectations. This may be done either individually or in groups
Group member leaves the group	When a group member specifically tells the facilitator that that they do not want to attend the group, or when they have not attended the group for a number of weeks without there being a clear reason for, the facilitator should use their clinical judgement to make a decision about when they should be considered as having left the group. At this stage the facilitator will write to the patient confirming that their place in the group has closed
Replacing a group member with another patient	When it is agreed that a patient has left the group, the facilitator should notify the trial co-ordinator, who will make a note that there is a space in the group that can be filled by another study participant
Verbal aggression or violence	Facilitator to obtain and refer to risk assessment for all group members prior to their joining. In case of agitation/aggression/violence, the facilitator should use their clinical judgement to assess the situation and attempt de-escalation. The group member may need to be asked to leave the room. Inform the patient's care-co-ordinator, document the incident on the treatment fidelity pro forma and complete incident form, etc. (as per usual clinical practice). Patients may be asked to stay away from subsequent groups (such a decision should be discussed with clinical supervisor)
Deteriorating mental state	Where a participant's mental state shows clear signs of deteriorating the facilitator should encourage the patient to discuss this with their care co-ordinator or psychiatrist. If the situation continues to deteriorate the facilitator should seek verbal consent from the patient to contact their care co-ordinator. In consultation with their supervisor and following review of their risk assessment and care plan, there may be circumstances in which the facilitator will need to contact the patient's care co-ordinator even if consent is withheld
Therapist leaves local services or sick leave, etc.	When long gaps look likely, the situation should be discussed with the local supervisor and efforts made to identify a new facilitator. Participants should be given as much notice of this as possible

Appendix 2

Differences in group processes and response to adverse events in art therapy and activity groups used in the trial

Aspect of structure or content	Activity groups	Art therapy groups
Late attendance	Remind client about starting times	Use clinical judgement when deciding how to explore reasons for late attendance/feelings about the group
Conflict with facilitator/therapist or other group members	Make efforts to help the patient calm themselves, try to refocus patient on group activities and try to take steps to avoid escalation of the situation	Use clinical judgement to enquire about reasons for conflict and understand the behaviour in terms of their art work, group processes and other factors in the patient's life
Annual leave/sick leave	The MATISSE group supervisors should discuss this with individual group facilitators, but we suggest that every attempt is made to avoid absence of facilitators during the first few weeks of the study. Once a group has become established short periods of leave should be managed by the co-facilitator	If the art therapist is unable to attend the group, the group will be cancelled Wherever possible the group will be notified in advance and space provided for members to process this
Handling psychological material	If participants raise psychological concerns these should be handled in a sensitive, client-centred manner by the facilitator. Diversionary methods may be used to help participants focus on group activities as a means of distracting themselves from their symptoms. Participants may also be encouraged to raise their concerns with their key worker Psychological concerns will not be explored in these groups and interpretations of participants' behaviours or comments must not be provided	Art therapists should use their clinical judgement to decide how to help participants express themselves both verbally and through the use of images. Experiences of distress may be considered in the context of factors occurring in their lives and the outside world, but may also be thought about in relation to group processes and their use of art materials. Although therapists may sometimes suggest links between art work and the persons' mental state or history, therapy is generally focused on the 'here and now'. Efforts to address the content and meaning of art work produced by a person who is acutely psychotic need to be handled with utmost sensitivity or avoided
Group facilitator leaves	Changes in group facilitator should be explained ahead of any change wherever possible	Opportunities for exploring participants' feelings about changes of facilitator should be made available

Appendix 3

Unit costs and sources for 2007–8 used in the economic analysis

Service	Unit cost (£)	Source
Accommodation		
Bed and breakfast (week)	176	Finn *et al.*[73]
Hostel, shelter, refuge (week)	94	Curtis[41]
Staffed accommodation (week)	485	Curtis[41]
Hospital		
Inpatient, mental health (night)	258	Department of Health[40]
Inpatient, other (per episode)	1409	Department of Health[40]
Outpatient (appointment)	34–289	Department of Health[40]
Accident and emergency (attendance)	117	Department of Health[40]
Accident and emergency (ambulance)	188	Department of Health[40]
Community health and social care services		
GP surgery (hour)	140	Curtis[41]
GP home (hour)	234	Curtis[41]
GP telephone (hour)	145	Curtis[41]
Practice nurse (hour)	29	Curtis[41]
Case manager (hour)	44	Curtis[41]
CPN (hour)	44	Curtis[41]
Psychiatrist (contact)	146	Department of Health[40]
Clinical psychologist (hour)	72	Curtis[41]
Home treatment team (contact)	200	Department of Health[40]
Crisis resolution team (hour)	27	Curtis[41]
Health visitor (hour)	83	Curtis[41]
Occupational therapist (hour)	38	Curtis[41]
Counsellor (hour)	40	Curtis[41]
Family therapist (hour)	40	Curtis[41]
Social worker (hour)	138	Curtis[41]
Home help (hour)	16	Curtis[41]
Day centre (session)	21	Curtis[41]
Drop-in centre (session)	21	Curtis[41]
Drug and alcohol worker (hour)	40	Curtis[41]
Advice service (contact)	24	Curtis[41]
Helpline (contact)	3	Samaritans[74]
Criminal justice		
Prison (nights)	71	HM Prison Service[43]
Police custody (nights)	372	Finn *et al.*[73]
Probation officer (hour)	138	Curtis[41]
Police (hour)	28	Finn *et al.*[73]
Solicitor (hour)	62	Legal Services Commission[44]
Crimes committed (crime)	122–1599	Brand and Price,[75] Dhiri and Brand[76]

Appendix 4

Study protocol

Full proposal

Version 10.0 (6 February 2009).

Project title

(04/39/04) Group art therapy for people with schizophrenia.

Study acronym

MATISSE *M*ulticentre study of *A*rt *T*herapy *I*n *S*chizophrenia: *S*ystematic *E*valuation.

Planned investigation

Research objectives

1. To test the value of group art therapy in people with schizophrenia being treated by secondary care services. We propose a parallel-design, controlled trial, with randomisation to one of three treatment arms: group art therapy plus standard care; a non-specific activity group plus standard care; or standard care alone.
2. To compare short- and long-term outcomes (global functioning, engagement with services, mental health and well-being, service utilisation, adverse events, satisfaction with care and quality of life) among people in receipt of these three treatments.
3. To examine the costs and cost-effectiveness of adjunctive art therapy compared to attention control and standard care alone.

Hypotheses

1. Among people with schizophrenia, group art therapy is associated with improved global functioning at 24 months compared to attention control treatment or standard care alone.
2. In the treatment of people with schizophrenia in secondary care settings, adjunctive group art therapy is more cost-effective than attention control treatment or standard care alone.

Secondary hypotheses

Among people with schizophrenia, group art therapy is associated with improved mental health (main secondary outcome), social functioning, engagement with services, and satisfaction with care compared to attention control treatment or standard care alone.

Our primary hypothesis is based on global functioning at 24 months. We have selected this time point because previous studies of psychosocial interventions for people with schizophrenia have demonstrated greatest improvements in global functioning in the year after the end of therapy.[1,2]

Existing research

Schizophrenia is a severe mental illness that affects up to one in 100 people at some point in their lives.[3]The illness is characterised by disturbances in thinking, perception and behaviour, combined with a decline in social functioning. Antipsychotic drugs were first introduced into psychiatric practice in the 1950s and have since become the mainstay of treatment. Large scale randomised trials have demonstrated their effectiveness in reducing the symptoms of schizophrenia and decreasing the likelihood of relapse. Nevertheless, many people with

schizophrenia are poorly adherent to their medication regimens, and a substantial proportion of those who are still experience residual symptoms, relapse and reduced social functioning.[4] Such problems have led to interest in adding psychological interventions to the package of treatment provided for people with schizophrenia. Over recent years, randomised trials of cognitive behaviour therapy and family therapy have demonstrated that psychological approaches to helping people with schizophrenia can lead to improvements in mental health and social functioning, and are now included in NICE guidelines for the treatment of schizophrenia. However, other psychosocial interventions such as social skills training and cognitive remediation have been shown to have little if any effect.[5]

Art therapy is a form of psychotherapy that has been practised for over 60 years.[6] Originally developed in Britain, it is now widely used in Europe and North America as an adjunctive treatment for a variety of medical and behavioural problems. Art therapy has been promoted as a means of helping to engage people in psychological treatment who may find it difficult to express themselves verbally. There are now over 1500 art therapists in Britain of whom more than 600 work primarily with people with mental health problems.[7]

Despite the widespread use of art therapy little research has been conducted to explore the effects of this intervention. Observational evidence from clinical populations has demonstrated high levels of acceptability and improvements in mental health.[8] In a randomised trial conducted by Green and colleagues in the United States, people assigned to group art therapy reported improved self esteem.[9] The authors speculated that art therapy led to increased engagement with services, though the only evidence to support this assertion was the lower proportion of dropouts among those assigned to the experimental arm of the study – a finding which is not atypical in randomised trials of psychosocial interventions.

More recently, Richardson and colleagues[10] compared the addition of 12 weekly sessions of interactive group art therapy to standard care among people with schizophrenia being treated in outpatient settings. In a small randomised trial of 90 participants, they demonstrated a statistically significant reduction in symptoms of schizophrenia at the end of three months. The study also found clinically (but not statistically) significant improvements in other outcomes including social functioning. Interpreting findings from this and other experimental studies of art therapy is complicated because they have lacked statistical power, used treatment periods much shorter than those generally used in clinical practice, and failed to assess treatment fidelity. As previous studies have compared active treatment with standard care alone, it is also possible that any benefits seen are the result of non-specific effects of contact time with therapists.

Having conducted a systematic review of the effectiveness of art therapy for people with schizophrenia Ruddy and Milnes[11] concluded that while randomised trials were feasible, 'its benefits, or harms, are unclear'. Studies examining the costs and cost-effectiveness of art therapy for people with schizophrenia have not been conducted.[11]

In the present state of knowledge, we judge that a multi-centre, parallel-design randomised trial comparing adjunctive group art therapy, attention control treatment, and standard care alone, in which a pragmatic design is followed and in which cost-effectiveness is a major component, is the best way of evaluating art therapy for people with schizophrenia.

Research methods

Design

A three-arm, parallel, randomised, controlled trial of referral to group art therapy plus standard care, referral to an attention control 'activity' group plus standard care, and standard care alone.

Setting

Study participants will be recruited from secondary care settings: inpatient units, intermediary services such as day hospitals, and case lists of community mental health teams (including sector teams, assertive outreach teams, early intervention services and other community-based services).

Study sample (including inclusion/exclusion criteria)

All those treated by secondary care services in study centres who are aged 18 years or over and have a clinical diagnosis of schizophrenia, confirmed by an examination of case notes using operationalised criteria (OPCRIT),[12] will be eligible to take part in the study, with the exception of those who:

- are unwilling to provide written informed consent
- speak insufficient English in order to complete baseline assessment
- have severe cognitive impairment, and
- those who are already receiving art therapy or another of the arts therapies (music therapy, drama therapy, or dance/movement therapy).

We have deliberately limited the exclusion criteria in order to increase generalisability of study findings. For each participant, we will record the date of the first presentation to services with schizophrenia, but we will not restrict recruitment to people in a specific stage of the illness because available evidence does not support the notion that the intervention has differential effects for people with sub-types of the disorder. While people who are currently receiving art therapy or another of the arts therapies (music, drama therapy, etc.) will be excluded, we will not exclude the minority of participants who will be in receipt of other forms of structured psychosocial intervention.

The study sample will be recruited from hospital and community services in four centres: Centre 1 – West London; Centre 2 – North London; Centre 3 – Avon and Wiltshire; Centre 4 – Northern Ireland. Centres have been selected because they each have established systems for delivering art therapy for people with schizophrenia and for supervising and supporting arts therapists. The four centres include a mix of inner city, urban, semi-rural and rural settings and serve a population that includes people from a variety of different ethnic communities. Mental health services in these areas are provided by four Mental Health Trusts and three Health and Social Care Trusts. Each centre has a track record of user involvement in research and all but one have close association with the Mental Health Research Network of the National Institute for Mental Health (England). We would work in partnership with the Network in order to facilitate recruitment of people into the study.

Interventions

The study applicants and collaborators have been at the forefront of developing and evaluating art therapy in the UK. Group art therapy will be provided in accordance with national recommendations on this intervention developed by the British Association of Art Therapists (www.baat.org/). It is the model of art therapy most commonly taught in approved Art Therapy training in the UK.[15] Our attention control treatment, 'activity groups', is based on an intervention that was successfully used as an attention control treatment in a recent randomised trial of art therapy.[16] We have selected this intervention because it is similar in form and content to groups already offered to people with schizophrenia in secondary care settings and discussions with user groups and individual service users who have schizophrenia suggest that this is a form of control treatment that will be acceptable to them. Activity groups will allow us to control for the non-specific effects of social interaction in groups and for therapist time, but they will not include the

image making or psychotherapeutic elements that are purported to be the active ingredients of group art therapy.

All art therapists and facilitators of activity groups will attend an induction day prior to the start of the study. The induction day will ensure that all therapists understand the focus, aims and therapeutic stance to be used during the study.

Experimental treatment – group art therapy Group art therapy is a complex intervention based on a synthesis of concepts from psychotherapy[17–19] and art therapy.[13,14] It aims to promote group processes such as group cohesiveness (as members learn to trust the group they can share deep and difficult feelings without fear of ridicule) and interpersonal learning (the opportunity for receiving feedback and contributing to others' ability to change) through the use of art materials. The use of art materials provides a means of expression additional to or alternative to words. In patients with schizophrenia who have difficulty managing confusing thoughts making a drawing or painting in the presence of other group members and the therapist provides a focus. It does not matter if the images are jumbled as the art work is not being judged on aesthetic grounds. The group can retain the images, focus on them during the group, return to them the following week, add to them and build up both an individual and group visual presence.

Sometimes images may be disturbing (as are the emotions which have led to them) so the therapist ensures that there is plenty of time for them to be 'processed' – that is, discussed in the group and the disturbing feelings fully addressed. The practical nature of the group provides a structure which is, for many people, less threatening than a verbal group. They can, if they need, preoccupy themselves with the art materials and titrate their degree of social exposure more effectively than may be possible in a verbal group. They may begin to enjoy 'playing' with and experimenting with the materials which may provide relief to people with long term mental health problems.

Guidelines for group art therapy for people with schizophrenia were published by Waller and colleagues,[13,14] they include the following:

- *Setting* Sessions take place in a safe and consistent environment that offers privacy, and confidentiality, and is suitable for the use of art materials.
- *Boundaries* Sessions take place at a regular time and patients are encouraged to attend on time and stay for the whole session. Patients agree not to damage their work or the work of other members of the group. The therapist undertakes to look after artwork and keep all artwork in a safe place.
- *Role of the therapist* To encourage open communication, be attentive to group processes, and help the group to maintain boundaries. The therapist aims to facilitate understanding and learning about processes within the group.
- *Therapeutic stance* Non-directive, patients are encouraged to use art materials to express themselves freely and spontaneously. The therapist emphasises the resources that patients' have to make their own decisions. Everything that happens during therapy, including the produced art work, spoken words, and actions, is understood as a potential communication in the context of the relationship between patient, the therapist, and the group.

The art therapists who will be involved in the study have confirmed that they already work within these guidelines and will continue to work within them during the course of the trial. All art therapists involved in the study will have trained on courses approved by the Health Professions Council, and be current registrants of the HPC. All therapists taking part in the study will receive regular weekly group supervision from a senior art therapist in keeping with existing practice

at each of the four study centres. Groups will be co-facilitated by an assistant who is not an art therapist. Groups will last 90 minutes, with a maximum of eight clients per group, and run for a period of 12 months.

Active control treatment – activity groups The aim of these groups will be to control for the non-specific effects of art therapy associated with time spent with a therapist, and the opportunities for social interaction resulting from membership of a weekly group. Activity groups will incorporate a range of activities that reflect the content of local groups provided for people with schizophrenia including social interaction, themed discussion and games. Therapists will suggest activities for the group, but will also be responsive to preferences of group members. Activity groups will not provide opportunities for participants to express themselves through use of art materials. If participants raise psychological concerns they will be handled in a sensitive, client-centred manner by the facilitator and they will be encouraged to raise their concerns with their key worker. Psychological concerns will not be explored in these groups. Groups will be facilitated by mental health workers with previous experience of running groups for people with schizophrenia and co-facilitated by an assistant. Facilitators will be drawn from those with a range of different backgrounds but qualified occupational therapists will not be included. All therapists facilitating activity groups will receive regular weekly group supervision from a senior health care professional.

Activity groups will be organised along similar lines to art therapy groups: they will be co-facilitated; take place once a week for 90 minutes; run for 12 months; and have a maximum of eight members per group.

Control treatment – standard care alone Participants randomised to control treatment will continue to receive standard care from mental health services. This will include assessment of needs, pharmacotherapy, care planning, and the option of referral to other specialist services in line with usual practice. They will not have access to art therapy or other arts therapies until after all follow-up data has been collected. We will collect detailed information on all services that participants receive in all three arms of the trial throughout the study period using interviews and an examination of written and electronic records.

Treatment fidelity Facilitators of all art therapy and activity groups will be asked to complete a short proforma at the end of each group. The proforma will enable the facilitator to make a quick note of the structure and content of the group including:

1. the number of people who attended
2. any breaches of group boundaries and how these were addressed by the facilitator (such as people arriving late/leaving early, disruptions to the group by non-group members, conflicts between group members)
3. the verbal content of sessions and the responses that group facilitators made to verbal content
4. *art therapy groups only* art materials that were made available and used by the group
5. *activity group only* principal activity pursued in the group and how decisions about the content of group work were made.

Training for art therapists and group facilitators before the start of the trial will ensure a uniform approach to completion of the proforma. During the treatment phase of the trial, therapists and group facilitators will take the completed proforma to weekly group supervision sessions for discussion. Group supervision for art therapists will be provided by a senior art therapist within each Mental Health Trust, group supervision will be provided by a senior occupational therapist or other suitably qualified mental health care professional. This material will assist supervisors in

ensuring that art therapy and activity groups adhere to study guidelines, in particular, that group boundaries are maintained in all groups and that psychological processes are not explored in activity groups.

At the end of the study, proforma from all centres will be collected by the research team and a random sample of 50 (25 from art therapy groups and 25 from activity groups) per study centre (i.e. 200 in total) will be examined for treatment fidelity. The data recorded in section three, 'verbal content of sessions and responses made by group facilitators' will be extracted. Specific references to the type of group will be removed and an independent art therapist, masked to what type of group the data was extracted from, will rate each extract as coming from either an art therapy group or an activity group.

Data requirements

At baseline, we will collect demographic and clinical data including; age, gender, ethnicity, highest level of educational achievement, employment status, housing status, date of first presentation to clinical services with schizophrenia, primary and secondary clinical diagnosis, current medication, and previous receipt of structured psychosocial interventions including arts therapies. Written records will be used to generate a psychiatric diagnosis using operationalised criteria,[12] and an interview conducted to establish:

1. *Global functioning (primary outcome)* using the Global Assessment of Functioning Scale (GAF).[20] The GAF is a 100-point single item, observer-rated scale that rates functioning on a continuum from health to illness. The GAF can only be completed once a more detailed assessment of the person's health and social functioning has taken place, but only takes 1–2 minutes to complete. It is a reliable and valid measure of global functioning, has been widely used in previous studies of people with schizophrenia, and is sensitive to change.[21]
2. *Mental health (main secondary outcome)* using the Positive and Negative Syndrome Scale.[22] This is a 30-item rating scale which is accompanied by a structured interview. It takes approximately 30 minutes to complete and has been widely used to examine changes in symptoms in people with schizophrenia and related psychoses.
3. *Medication* we will record all medication being prescribed to participants and assess concordance using the Morisky Scale,[23] a four-item questionnaire which provides a valid estimate of use of psychotropic medication.
4. *Health related quality of life* using EuroQol EQ-5D.[24] This is a generic measure for describing and valuing health-related quality of life. The measure includes a rating of own health in five domains (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) and a rating of own health by means of a visual analogue scale (0–100). It has been extensively used and its psychometric properties are adequate;
5. *Cost data* using a modified version of the Client Service Receipt Inventory.[25]

Additional information will be collected from self-completed questionnaires covering:

6. *Social function* using the Social Function Schedule,[26] a widely used self-completed measure of social function with established reliability and validity.
7. *Well-being* using the General Well-Being Scale,[27] an 18-item self report scale. This instrument was originally developed for the US Health and Nutrition Survey, but has subsequently been used in studies of people with schizophrenia and has good psychometric properties.[27]
8. *Satisfaction with services* using the Client Satisfaction Questionnaire 28, *an 8-item measure that has been widely used in previous studies and is sensitive to change.*
9. *Patient preference* patients will be asked which, if any, of the three arms of the trial they would prefer to be in.

Finally, we will obtain data from the participant's key worker on:

10. *Engagement with services* using the 4-item Service Engagement Scale.[29]
11. *Occupational and housing status* indicating whether the participant lives in supported/independent accommodation and the degree of support provided, together with a short description of any paid work, voluntary work or educational/training activities undertaken by the participant during the previous 6 months.
12. *The incidence of adverse events* we will ask the participant's key worker to complete a short proforma detailing any incidents of suicidal behaviour, violence or aggression. The proforma will be based on the one used by Johnson and colleagues[30] for a large-scale study of community health teams in a representative sample of people with psychosis.
13. *Global functioning* using the Global Assessment of Functioning Scale (GAF).[20] In instances where it has not been possible for the researcher to obtain a GAF score from a participant we will explore whether GAF score from the person's key worker provides a valid alternative measure of our primary outcome.

At 12- and 24-month follow-up all items (1–13 above) will be repeated. Following the collection of all the 24-month follow-up data, participants' electronic and written records will be examined to obtain details of any period of inpatient treatment received during the previous 2 years. We will note whether admissions were on a compulsory or voluntary basis, and the number of contacts with emergency hospital services and crisis teams. These data will also provide a complementary source of data for the economic evaluation since days in hospital is often found to be the key cost driver in this patient population.

We will seek written informed consent to photograph each art work produced by members of art therapy groups using a digital camera. These images would be deleted, along with other study data, five ten after the end of the trial. We will also seek written informed consent from art therapists and activity group coordinators in order to obtain details of their background, clinical experience and data on their attitudes to patients and the treatment of people with schizophrenia. We believe that this material, combined with process data from proforma completed by art therapists, and quantitative outcome data from the trial, provides an important source of data through which to explore the relationship between the process and outcomes of art therapy. This constitutes a supplementary project which we consider would add value to the main outcome study. Thus, the study applicants, together with other collaborators in the Art Therapy Research Practice Network, will pursue additional funding from research councils and charities to allow this work to be undertaken.

Study procedures

Preparation and recruitment Prior to the start of the study, all researchers will be trained in the use of the study instruments and assessments. We will use practice interviews with local service users in order to examine inter-rater reliability of GAF scores. We will also organise an induction day for all art therapists and their supervisors and another for all activity group facilitators and their supervisors (see *Interventions*, above). These sessions will be used to ensure that those delivering and supervising art and activity groups are familiar with study procedures and guidelines for delivering interventions during the study period.

In each centre researchers will publicise the study through meetings with staff at local inpatient units, community teams, day centres and residential units. Researchers will visit wards and teams every week and residential units every fortnight throughout the nine month recruitment period in order to remind staff about the study and promote recruitment of potential participants. Clinical staff will be given a copy of an information sheet which summarises the study protocol and helps them identify patients who may be suitable for the study. In partnership CSOs

from the MHRN Hubs, clinical staff will identify potential participants and facilitate the CSOs or researchers to assess eligibility to participate in the trial, provide written and verbal information, obtain written consent and collect baseline data. Collection of baseline data will involve interview, completion of questionnaires and completion of the engagement and adverse events proforma by the participant's key worker. The researcher will only complete the Global Assessment of Functioning Scale once all other data from participant's interview and questionnaires has been collected. Participants will then be randomised.

Treatment allocation Remote telephone randomisation will be undertaken independently by an independent statistician based at the Medical Research Council General Practice Research Framework. Equal numbers of participants will be randomised to each arm of the three arms of the trial. We will use a minimisation scheme to balance potential confounding variables (age – one of three bands below 30, 30 to 45, and above 45, sex, and centre) across the three arms of the trial. Participants, their key worker and their GP will be notified of allocation status by an independent administrator. The administrator will simultaneously inform local art therapists or activity group workers of allocation status of the participant so that arrangements can be made for the participant to receive their allocated intervention while the local researcher will remain masked.

In keeping with normal clinical practice, art therapists and activity group facilitators will try to take demographic and clinical factors into account when allocating participants to groups. In each centre four art therapy groups and four activity groups will be set up during the first phase of the study. In some instances participants will need to be assigned to the only available group, but in most centres there will be more than one local group, and facilitators will be able to make decisions about which group a new participant is allocated in order to maximise group cohesion (e.g. avoiding groups that contain only one woman, or BME service user).

Follow-up Maintaining masking of assessors is crucial and any accidental un-masking will be recorded systematically and corrective action taken. Rater 'masking' will be maintained by providing specific instructions to participants and their clinical teams not to disclose treatment details. Data will be held securely and all personal identifiers will be removed, with randomisation details held separately and password protected. Contact with the trial interventions will be monitored through records so that the researchers are not unblinded by asking for this information when collecting the service-use data. We will follow up participants at 12 (end of therapy), and 24 months after randomisation. This level of follow up is in keeping with other trials which have demonstrated changes in health and social functioning among people with schizophrenia who are offered psychosocial interventions. We do not believe that additional resources required to obtain more frequent measures of outcome would therefore be justified. Participants completing the follow-up interviews will be offered a £15 honorarium in recognition of any inconvenience related to their involvement in the study.

Data management Each study participant will be assigned a unique trial identification number at the start of the assessment process. This number will be written on all datasheets used to record exposure and outcome data on study participants. A hard copy of a record sheet linking patient identity, contact details and trial identification number for all participants will be kept at each site. It will be placed securely in a locked filling cabinet separate from datasheets. All datasheets will be photocopied at source, with one copy retained by researchers at each site, and the other posted by recorded delivery mail to the trial administrator at Imperial College for data entry. Each time data are posted a log sheet providing details of the date and time of the interview and the date when material was posted will be faxed to the trial administrator. Log sheets will be faxed back to researchers by the trial administrator to confirm that data was received and raising any queries about missing data or other discrepancies. All data will be double entered onto a

database and checked for errors before being transferred to a Stata file for data analysis. All data will be kept secure at all times and maintained in accordance with the requirements of the Data Protection Act. Study data will be destroyed ten years after the end of the trial.

Sample size

The sample size calculation for the study is based on the primary hypotheses: that those referred to group art therapy will have improved global functioning at 24 months compared to those referred to attention control treatment or those who receive standard care alone, and that adjunctive group art therapy is more cost-effective than attention control treatment plus standard care or standard care alone. Global functioning was not assessed in the two previous randomised trials of art therapy for people with schizophrenia, so we have used data on mean GAF scores and SDs from recent trials of Compliance and Cognitive Therapy for people with schizophrenia. These interventions have demonstrated an improvement in GAF scores of between 5 and 10 points.[1,2] We have powered this trial to be able to detect a difference in GAF score of 6 points. A GAF score of 56 (moderate to severe impairment) equates to a person struggling to maintain employment, a GAF score of 50 (severely impaired function) would be assigned to someone being unable to keep a job.

To detect a mean difference in global functioning of 6 points on the GAF (SD = 10.0) at 24 months with a two-sided significance level (α) of 5% and power ($1 - \beta$) of 80% would require 45 patients in each arm of the trial. In a trial of group art therapy there is likely to be clustering of the intervention effect around therapists.[31] In our recent trial of music therapy for people with schizophrenia we observed an ICC of 0.125.[32] However we believe that group processes may lead to a greater clustering of effects and have decided to use an ICC of 1.75 for this trial. With an estimated cluster size of 8 and an ICC of 1.75 the Design Effect for the trial = 2.22 and a sample size of 100 per group is therefore required.

A sample of 100 participants in each of the three arms of the trial would be sufficient to detect a difference of 50% in mean costs, at the 5% level of significance and with 80% power. Differences of this magnitude are consistent with cost data reported in the literature. For example, Haddock and colleagues[33] estimate an approximate 50% relative difference in 18-month total costs between CBT and standard care in the treatment of people with schizophrenia and comorbid substance misuse problems.

In anticipation of loss to follow up and uptake of group treatment, we will randomise 417 participants during the course of the study, 104 at each centre. We will obtain informed consent from participants to examine written and electronic records and use these to obtain data on direct costs of healthcare, where complete economic data from participants can not be obtained.

Statistical analysis

All primary statistical analysis will use the intention-to-treat principle. We will use multiple imputation to account for missing data before the data is analysed.[34] Multiple imputation is based on the assumption that data is 'missing at random'.[35] In the event that this assumption is violated, due for instance to differential loss to follow-up in the three arms of the trial, we will adjust for this by modelling the missing data mechanism.[36]

Descriptive analysis including tables and graphs of baseline demographic and clinical variables will be produced. This will be followed by simple associations and correlation coefficients with their 95% CI. For the primary outcome measure (global functioning), we will also examine differences in mean score between those randomised to each of the three arms of the trial using analysis of variance. Univariate regression analysis models will be fitted to locate possible predictors of the main outcome.

We anticipate that there will be clustering of outcomes as a result of patients being assigned to groups facilitated by different therapists. Such clustering violates the assumption that observed outcomes of individuals are independent and can result in increased standard errors.[31] To take account of this a two level multi-level model will be fitted, with patients as level one and the therapist as the second level, this will take account of heterogeneity in the outcomes and treatment across therapists. The model will include baseline variables as covariates in the patients' level, if they were found to have prognostic effect in the univariate regression analysis. The fact that therapists within each of the four centres in this multi-centre trial may also be similar will be accounted for by adjusting for the centre in the therapist level of the hierarchical model. The statistical package Stata (version 8.0) will be used for all the descriptive analysis, graphs and univariate regression models. For the analytical multi-level analysis MLwiN (version 2.01) will be used.

The economic evaluation will be conducted from the societal perspective, covering services received (including health, social services, voluntary sector services, housing support and contact with criminal justice services) and any productivity losses. Unit costs will be attached to resource use, using the best available estimates of long run marginal opportunity cost, to obtain a cost per person over the entire period of participation in the trial. Local unit costs will be used where possible, with national estimations where necessary. Total average costs will be linked with the primary clinical outcome measure in the form of a cost-effectiveness analysis. Cost-effectiveness will be examined using the net-benefit statistic,[37] a reformulation of the cost-effectiveness decision rule that does not rely on cost-effectiveness ratios with their associated statistical problems. This will allow the cost-effectiveness analysis to be formulated within a standard regression type framework.[37]

A secondary economic evaluation will consider cost-effectiveness in terms of quality adjusted life-years, using the EQ-5D measure of health related quality of life, allowing the relative cost-effectiveness of art therapy to be explored across a broader range of health care interventions. Finally, to ensure no important effects are excluded, a cost-consequence analysis will be carried out to explore the relationship between cost and all other secondary outcome measures.[38] Sensitivity analyses will be performed to check the assumptions made in the cost calculations and analyses and to explore the generalisability of the results to the UK as a whole.

Ethical arrangements

Multi-centre and Local Research Ethics Committee approval will be obtained prior to the start of data collection. Only those who agree to provide written informed consent will be included in the study. Each potential participant will be provided with a copy of an information sheet that includes a contact number for the study team.

Risks and benefits for trial participants We are not aware of any evidence that art therapy can harm people who have schizophrenia. However, we will ensure that data on all adverse incidents available to our Independent Data Monitoring and Ethics Committee. Should levels of self-harm or other adverse incidents exceed those of comparable studies, the IDMEC will have the power to ask to see data on levels of incidents among participants in each arm of the trial and to decide what action should be taken.

Participants in all three arms of the study will be asked to give up their time to take part in study interviews and to complete study questionnaires. Study interviews will last no longer than 90 minutes, with four interviews taking place over the two-year study period. We will reimburse any travel or other costs incurred by participants. All participants will be offered £15 honoraria after completion of 24-month follow-up interviews. Those who are randomised to the 'standard care alone' arm of the study will be offered the opportunity to have a place in an art therapy group at the end of the two-year study period (see *Design*, above).

Research governance

We have been advised that this trial would not need to conform to the EU Clinical Trials Directive [2001/20/EC]. However in accordance with high standards of research governance we would ensure researchers receive training in the International Conference on Harmonisation (ICH) Guidelines – Good Clinical Practice, set up a Trial Steering Group (TSC) and an Independent Data Monitoring and Ethics Committee (IDMEC) prior to the start of the study.

The TSG would comprise study applicants, a representative of the HTA, and representatives of service users and providers (see *Consumers*, below).

An IDMEC will be established to monitor (1) recruitment of study participants, (2) the incidence of adverse events, (3) ethical issues, (4) any other factors that might compromise the progress and satisfactory completion of the trial. This will be Chaired by Professor Julian Leff (Emeritus Professor of Social Psychiatry at Institute of Psychiatry, Kings College London) and include an independent statistician (Dr Bob Blizard) and Dr Deborah Rutter, who is a research associate at Imperial College and a member of a Local Research Ethics Committee.

Project timetable and milestones

Key milestones

- Confirm assessment tools, patient information sheets Spring 2006.
- Obtain MREC approval for the study July 2006.
- Start date 01.10.06.
- First meeting of IDMEC 23.11.06.
- Second meeting of IDMEC 22.02.07.
- Third meeting of IDMEC 23.05.07.
- Completion of recruitment 31.06.08.
- Completion of collection of follow-up data 31.06.10.
- Submit final study report 31.09.10.

Expertise

Study applicants

Study applicants comprise a multi-disciplinary team of academics and clinicians. Three applicants – Dr Mike Crawford, Dr Helen Killaspy and Professor Diane Waller – will act as joint-lead applicants. All co-applicants will play a role in project management and communication of study findings through membership of the Trial Steering Group. Applicants will also make the specific contributions listed below.

Name	Post	Contribution
Dr Mike Crawford (MC)	Senior Lecturer in Psychiatry	Joint-lead applicant – project management Principal Investigator – West London
Dr Helen Killaspy (HK)	Senior Lecturer in Psychiatry	Joint-lead applicant – project management Principal Investigator – North London
Professor Diane Waller (DW)	Professor in Art Psychotherapy	Joint-lead applicant – co-ordination and overview of the art therapy process
Mr Gerhart Knerer (GK)	MRC Health Economist	Economic evaluation, data analysis
Dr Ula Nur (UN),	MRC Statistician	Data analysis, handling missing data
Dr David Osborn (DO)	Senior Lecturer in Psychiatry	Delivery of activity control treatment
Dr Tony Johnston (TJ)	Senior Statistician	Supervision of all data analyses
Professor Thomas Barnes (TB)	Professor of Clinical Psychiatry	Data collection – West London, and training on use of rating scales
Professor Scott Weich (SW)	Professor of Psychiatry	Supporting recruitment
Ms Anna Maratos (AM)	Head of Arts Therapies	Supporting trial management
Ms Katie Clayton (KC)	Lead Therapists	Supervision for art therapists
Dr Tony Soteriou (TS)	Director of R&D	Principal Investigator – Avon and Wiltshire
Dr Tony O'Neil (TON)	Senior Lecturer in Psychiatry	Principal Investigator – Northern Ireland
Professor Peter Tyrer (PT)	Professor of Community Psychiatry	Oversee study methods and data analysis
Professor Michel King (MK)	Professor of Primary Care Psychiatry	Oversee study methods and data analysis

Study applicants bring expertise in the following areas:

- conducting randomised trials of complex psychosocial intervention (PT, MK, SW, TB, TJ, SB, MC, HK, DO)
- research into the process and outcomes of arts therapies (DW, HOM, AM, SL, MC)
- evaluating interventions for treatment of people with schizophrenia (TB, HK, DO, SB, MC, PT, MK)
- health economics (SB, GK)
- medical statistics/handling missing data (TJ, UN, GK)
- involving service users in research (MC, MK, HK).

We will also draw on a range of collaborators with expertise in: facilitating user involvement in research (Rogan Woolf, User Support Worker, North London Hub of MHRN and Steven Scott Chair of Service User Research Forum) and art therapy practice and research (Dr Chris Evans, Consultant Psychotherapist, Nottinghamshire NHS Trust and Kathy Killick, Art Therapist, Katie Clayton, Lead Art Therapist Camden and Islington Mental Health Trust).

Supervision of research and clinical staff

Responsibility for the project will rest with MC who will work in collaboration with HK, DW and other study applicants. The project co-coordinator will be supervised by MC. Each of the four researchers will receive weekly supervision from MC (West London), HK (North London), TS (Avon and Wiltshire), and TON (Cambridge and Peterborough).

Consumers

It is clear from our preliminary contact with user groups that consumers welcome the proposed study. Lack of availability of psychosocial treatments is a concern often voiced by service users, and we intend to draw on the expertise of service users throughout the course of the project. Rogan Woolf (User Involvement Coordinator for the North London Hub of MHRN) will assist in coordinating user involvement in the project, and will work in close collaboration with Scott Stevens who is a service user who chairs SURF (Service User Research Forum). Rogan Woolf and Scott Stevens will both be appointed to the Trial Steering Group which will monitor study

progress and overseeing all other aspects of the study. Mr Stevens will also chair a User Reference Group comprising patients and carer's of people who have schizophrenia. The User Reference Group will meet on four occasions during the course of the study and play an important role in:

- assisting in the design of participant information sheets and consent forms
- advising us on the methods we will use for providing feedback on the study to study participants
- contribute to the process of communicating study findings. In addition to assisting us with the production of the final project report, members of the User Reference Group will be asked too help us prepare a summary of study findings suitable for publication is a service user journal.

Service users have already contributed to the design of the study; with feedback from qualitative interviews with service users resulting in our amending our secondary outcome measures by including a measure of well-being (please see previous correspondence).

Justification of support required

The majority of costs are those associated with employing research workers, and input from a part-time study coordinator, statistician and health economist. Additional costs of been kept to a minimum in order to deliver value for money.

Staff The project requires a part-time project coordinator who has previous experience coordinating multi-centre studies. The coordinator will play an important role in organising meetings, supporting research workers, facilitating user involvement on the project, and assisting with other administrative duties. Four full time researchers, one at each study site, will be responsible for recruiting study participants and collecting baseline and follow-up data. We have also costed for the help of a statistician and health economist (15% in year one, 10% in year 2 and 25% in year three), and for consultancies for DW, HOM and KK.

Travel Travel costs have to meet the needs of this multi-centre study with off-peak standard fare intercity travel for collaborators to attend meetings in London. Costs of travel by local public transport for follow-up interviews are also included.

Materials and consumables Stationery and photocopying costs associated with data collection have been added. Honoraria will be offered to all study participants at the end of data collection (£15 per participant) and for unwaged service users who are members of the Trial Steering Group (£50 per meeting),

Exceptional items This will cover costs for advertising posts and paying for independent randomisation by the Clinical Trials Unit at the Institute of Psychiatry.

Equipment These cover the costs of four computers with printers and four digital cameras. For health and safety reasons we will provide a mobile telephone for each of the researchers collecting field data.

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Health Technology Assessment programme

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